



FEDERAL REGISTER

Vol. 82 Friday,
No. 144 July 28, 2017

Pages 35057–35434

OFFICE OF THE FEDERAL REGISTER



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

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

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

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

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

The online edition of the **Federal Register** is issued under the authority of the Administrative Committee of the Federal Register as the official legal equivalent of the paper and microfiche editions (44 U.S.C. 4101 and 1 CFR 5.10). It is updated by 6:00 a.m. each day the **Federal Register** is published and includes both text and graphics from Volume 59, 1 (January 2, 1994) forward. For more information, contact the GPO Customer Contact Center, U.S. Government Publishing Office. Phone 202-512-1800 or 866-512-1800 (toll free). E-mail, gpocusthelp.com.

The annual subscription price for the **Federal Register** paper edition is \$749 plus postage, or \$808, plus postage, for a combined **Federal Register**, **Federal Register** Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the **Federal Register** Index and LSA is \$165, plus postage. Six month subscriptions are available for one-half the annual rate. The prevailing postal rates will be applied to orders according to the delivery method requested. The price of a single copy of the daily **Federal Register**, including postage, is based on the number of pages: \$11 for an issue containing less than 200 pages; \$22 for an issue containing 200 to 400 pages; and \$33 for an issue containing more than 400 pages. Single issues of the microfiche edition may be purchased for \$3 per copy, including postage. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA, MasterCard, American Express, or Discover. Mail to: U.S. Government Publishing Office—New Orders, P.O. Box 979050, St. Louis, MO 63197-9000; or call toll free 1-866-512-1800, DC area 202-512-1800; or go to the U.S. Government Online Bookstore site, see bookstore.gpo.gov.

There are no restrictions on the republication of material appearing in the **Federal Register**.

How To Cite This Publication: Use the volume number and the page number. Example: 82 FR 12345.

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

SUBSCRIPTIONS AND COPIES

PUBLIC

Subscriptions:

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

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

Single copies/back copies:

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

FEDERAL AGENCIES

Subscriptions:

Assistance with Federal agency subscriptions:

Email FRSubscriptions@nara.gov
Phone 202-741-6000



Contents

Federal Register

Vol. 82, No. 144

Friday, July 28, 2017

Agency for Healthcare Research and Quality

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 35205–35212

Agriculture Department

See Animal and Plant Health Inspection Service
See Food and Nutrition Service

Alcohol, Tobacco, Firearms, and Explosives Bureau

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Federal Firearms License RENEWAL Application—ATF F 8 (5310.11) Part 11, 35239

Animal and Plant Health Inspection Service

NOTICES

Nonregulated Status; Determinations:
Bayer CropScience LP: Canola Genetically Engineered for Male Sterility and Glufosinate-Ammonium Resistance, 35172

Army Department

NOTICES

Exclusive Patent Licenses:
Hickies, Inc.; Brooklyn, NY, 35189

Bureau of Consumer Financial Protection

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals; Correction, 35189

Centers for Medicare & Medicaid Services

RULES

Medicare, Medicaid, and Children's Health Insurance Programs:
Extension of Temporary Moratoria on Enrollment of Part B Non-Emergency Ground Ambulance Suppliers and Home Health Agencies in Designated Geographic Locations, 35122–35125

PROPOSED RULES

Medicaid Program:
State Disproportionate Share Hospital Allotment Reductions, 35155–35171
Medicare and Medicaid Programs:
Home Health Prospective Payment System Rate Update, etc., 35270–35393

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 35212–35213

Children and Families Administration

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 35213

Civil Rights Commission

NOTICES

Meetings:
Louisiana Advisory Committee, 35180–35181

Coast Guard

RULES

Drawbridge Operations:
Lewis Creek Channel, Chincoteague, VA, 35094–35095
Navigation and Navigable Waters, and Shipping; Technical, Organizational, and Conforming Amendments, 35073–35093

Safety Zones:

Commencement Bay, Tacoma, WA, 35095–35096
Ogdensburg Summer Seaway Festival; Saint Lawrence Seaway, Ogdensburg, NY, 35099–35101
Wheeling Heritage Port Sternwheel Festival Foundation/
Wheeling Heritage Port Sternwheel Festival, Ohio River, Miles 90.2 to 90.7, Wheeling, WV, 35097
Whiskey Island Paddlefest, Lake Erie, Cleveland, OH, 35097–35099

Special Local Regulations:

EQT Pittsburgh Three Rivers Regatta, Pittsburgh, PA, 35093–35094
Wheeling Vintage Raceboat Regatta, Ohio River Miles 90.4–91.5, 35094

PROPOSED RULES

Safety Zones:

Huntington Beach Airshow, Huntington Beach, CA, 35138–35140

Security Zones:

Los Angeles Fleet Week, San Pedro, CA, 35136–35138

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 35235–35236

Commerce Department

See International Trade Administration

See National Oceanic and Atmospheric Administration

Committee for Purchase From People Who Are Blind or Severely Disabled

NOTICES

Procurement List; Additions and Deletions, 35187–35189

Defense Department

See Army Department

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 35190
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Environmentally Sound Products, 35204–35205

Energy Department

See Federal Energy Regulatory Commission

NOTICES

Authority To Import and Export Natural Gas and Liquefied Natural Gas:
Louisiana LNG Energy, LLC, Golden Pass Products, LLC, Freeport LNG Expansion, LP, FLNG, etc., 35190–35192

Environmental Protection Agency

RULES

Air Quality State Implementation Plans; Approvals and Promulgations:
Georgia; Miscellaneous Revisions, 35106–35109

Kentucky; Revisions to Louisville; Definitions, 35101–35104

Maryland; Requirements for Continuous Emission Monitoring, 35104–35106

Pesticide Tolerances:

Fenamidone, 35109–35115

Topramezone, 35115–35120

Tolerance Exemptions:

Pseudomonas chlororaphis strain AFS009, 35120–35122

PROPOSED RULES

Air Quality State Implementation Plans; Approvals and Promulgations:

California; Antelope Valley Air Quality Management District, 35149–35153

Georgia; Miscellaneous Revisions, 35149

Kentucky; Revisions to Louisville; Definitions, 35148

North Dakota; Revisions to Air Pollution Control Rules, 35153–35155

NOTICES

Environmental Impact Statements; Availability, 35200

Meetings:

Chartered Clean Air Scientific Advisory Committee and the Chartered Clean Air Scientific Advisory Committee Secondary National Ambient Air Quality Standards Review Panel for Oxides of Nitrogen and Sulfur, 35200–35201

Scientific Views:

Draft Updated Aquatic Life Ambient Water Quality Criteria for Aluminum in Freshwater, 35198–35200

Federal Aviation Administration

RULES

Class E Airspace; Amendments:

Bishop, CA, 35058–35060

Colorado City, AZ, 35060–35061

Class E Airspace; Establishments:

Del Norte, CO, 35057–35058

Willits, CA, 35061–35062

Special Conditions:

L–3 Communications Integrated Systems; Boeing Model 747–8 Series Airplanes, Large Non–Structural Glass in the Passenger Compartment, 35057

PROPOSED RULES

Airworthiness Directives:

Bombardier, Inc., Airplanes, 35127–35129

Class D and E Airspace, Establishments; Class E Airspace, Amendments:

Truckee, CA, 35129–35131

Class E Airspace, Establishments; Class D and E Airspace; Amendments:

Kaunakakai, HI, 35131–35133

NOTICES

Exemption Petitions; Summaries, 35260

Requests for Nominations:

National Parks Overflights Advisory Group, 35259–35260

Federal Deposit Insurance Corporation

NOTICES

Terminations of Receivership:

10383; BankMeridian, N.A.; Columbia, SC, 35201

10422; Patriot Bank Minnesota; Forest Lake, MN, 35202

Federal Energy Regulatory Commission

NOTICES

Combined Filings, 35192, 35194–35196

Environmental Assessments; Availability, etc.:

Marshall County Mine Panel 18W Project, 35196–35198

Environmental Impact Statements; Availability, etc.:
Atlantic Coast Pipeline and Supply Header Project, 35192–35194

Filings:

City of Alexandria, LA, 35196

Petitions for Enforcement:

Covanta Marion, Inc., 35196

Requests Under Blanket Authorizations:

National Fuel Gas Supply Corp., 35194

Federal Highway Administration

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 35261–35262

Federal Agency Actions:

MoPac (Loop 1) Intersections, Travis County, TX, 35260–35261

Federal Reserve System

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 35202–35203

Changes in Bank Control:

Acquisitions of Shares of a Bank or Bank Holding Company, 35203–35204

Federal Transit Administration

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 35262–35263

Food and Drug Administration

RULES

Medical Devices:

Cardiovascular Devices; Classification of Adjunctive Cardiovascular Status Indicator, 35065–35067

Gastroenterology-Urology Devices; Classification of Oral Removable Palatal Space Occupying Device for Weight Management and/or Weight Loss, 35067–35069

Neurological Devices; Classification of Cranial Motion Measurement Device, 35069–35071

Obstetrical and Gynecological Devices; Classification of Closed Loop Hysteroscopic Insufflator with Cutter–Coagulator, 35071–35073

NOTICES

Docket Establishments:

Drug Products That Present Demonstrable Difficulties for Compounding Under Federal Food, Drug, and Cosmetic Act, 35214–35216

Fostering Medical Innovation—Plan for Digital Health Devices; Software Precertification Pilot Program, 35216–35218

Food and Nutrition Service

NOTICES

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

Supplemental Nutrition Assistance Program Education Toolkit Intervention Submission Form and Scoring Tool, 35178–35180

Child and Adult Care Food Program:

National Average Payment Rates, Day Care Home Food Service Payment Rates, and Administrative Reimbursement Rates for Sponsoring Organizations of Day Care Homes for Period July 1, 2017 Through June 30, 2018, 35173–35175

Food Distribution Program:

Value of Donated Foods From July 1, 2017 Through June 30, 2018, 35180

National School Lunch, Special Milk, and School Breakfast Programs:

National Average Payments/Maximum Reimbursement Rates, 35175–35178

General Services Administration**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Environmentally Sound Products, 35204–35205

Health and Human Services Department

See Agency for Healthcare Research and Quality

See Centers for Medicare & Medicaid Services

See Children and Families Administration

See Food and Drug Administration

See Indian Health Service

See National Institutes of Health

Homeland Security Department

See Coast Guard

See U.S. Customs and Border Protection

Indian Health Service**NOTICES**

Delivery Area Designations:

Pamunkey Indian Tribe, 35227–35233

Funding Opportunities:

Domestic Violence Prevention Initiative, 35218–35227

Interior Department

See Land Management Bureau

International Trade Administration**NOTICES**

Antidumping or Countervailing Duty Investigations, Orders, or Reviews:

Certain Oil Country Tubular Goods From India, 35182–35183

Certain Oil Country Tubular Goods From Taiwan, 35181–35182

Chlorinated Isocyanurates From the People's Republic of China, 35183–35185

International Trade Commission**NOTICES**

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

Light-Walled Rectangular Pipe and Tube From Taiwan, 35238

Meetings; Sunshine Act, 35238–35239

Justice Department

See Alcohol, Tobacco, Firearms, and Explosives Bureau

Land Management Bureau**NOTICES**

Environmental Impact Statements; Availability, etc.:

Federal Coal Lease-by-Application in Decertified Powder River Federal Coal Production Region, WY, 35237–35238

Plats of Survey:

Oklahoma, Suspended, 35236–35237

Millennium Challenge Corporation**PROPOSED RULES**

Touhy Regulations, 35134–35136

National Aeronautics and Space Administration**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 35240

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

Environmentally Sound Products, 35204–35205

Intents To Grant Partially Exclusive Term Licenses, 35239–35240

National Foundation on the Arts and the Humanities**NOTICES**

Meetings:

Arts and Artifacts Indemnity Panel Advisory Committee, 35240–35241

National Institutes of Health**NOTICES**

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

Specimen Resource Locator, 35235

Meetings:

Center for Scientific Review, 35234

National Human Genome Research Institute, 35234

National Institute of Allergy and Infectious Diseases, 35234

National Institute on Alcohol Abuse and Alcoholism, 35233–35235

National Oceanic and Atmospheric Administration**RULES**

Fisheries of Exclusive Economic Zone Off Alaska:

Alaska Plaice in Bering Sea and Aleutian Islands Management Area, 35125–35126

Other Flatfish in Bering Sea and Aleutian Islands Management Area, 35126

NOTICES

Meetings:

Caribbean Fishery Management Council, 35187

Fisheries of South Atlantic; South Atlantic Fishery Management Council, 35186

Pacific Fishery Management Council, 35185–35186

South Atlantic Fishery Management Council, 35186–35187

Postal Regulatory Commission**NOTICES**

New Postal Products, 35241

Securities and Exchange Commission**RULES**

Adoption of Updated EDGAR Filer Manual, 35062–35064

NOTICES

Filings:

Public Company Accounting Oversight Board; Proposed Rules on Auditor's Report on Audit of Financial Statements, etc., 35396–35433

Self-Regulatory Organizations; Proposed Rule Changes:

Bats BZX Exchange, Inc., 35256–35259

Depository Trust Co.; Fixed Income Clearing Corp.;

National Securities Clearing Corp., 35241–35248

Financial Industry Regulatory Authority, Inc., 35248–35250

Investors Exchange, LLC, 35250–35254

Miami International Securities Exchange, LLC, 35254–35256
NYSE Arca, Inc., 35244–35245

State Department**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Refugee Biographic Data, 35259

Tennessee Valley Authority**PROPOSED RULES**

Procedures for Implementing National Environmental Policy Act, 35133

Transportation Department

See Federal Aviation Administration
See Federal Highway Administration
See Federal Transit Administration

Treasury Department**RULES**

U.S. Customs and Border Protection Regulations; Technical Corrections, 35064–35065

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 35264–35265
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Generic Clearance for Collection of Qualitative Feedback on Agency Service Delivery, 35263–35264
Multiple Alcohol and Tobacco Tax and Trade Bureau Information Collection Requests, 35265–35266
Multiple Internal Revenue Service Information Collection Requests, 35264

Meetings:

Federal Advisory Committee on Insurance, 35266–35267

U.S. Customs and Border Protection**RULES**

U.S. Customs and Border Protection Regulations; Technical Corrections, 35064–35065

U.S.–China Economic and Security Review Commission**NOTICES****Meetings:**

2017 Annual Report to Congress, 35267

Veterans Affairs Department**PROPOSED RULES**

Schedule for Rating Disabilities:
Genitourinary Diseases and Conditions, 35140–35148

Separate Parts In This Issue**Part II**

Health and Human Services Department, Centers for Medicare & Medicaid Services, 35270–35393

Part III

Securities and Exchange Commission, 35396–35433

Reader Aids

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

To subscribe to the Federal Register Table of Contents electronic mailing list, go to <https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new>, enter your e-mail address, then follow the instructions to join, leave, or manage your subscription.

CFR PARTS AFFECTED IN THIS ISSUE

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

14 CFR

25 35057
71 (4 documents) 35057,
35058, 35060, 35061

Proposed Rules:

39 35127
71 (2 documents) 35129,
35131

17 CFR

232 35062

18 CFR**Proposed Rules:**

1318 35133

19 CFR

159 (2 documents) 35064
181 (2 documents) 35064

21 CFR

870 35065
876 35067
882 35069
884 35071

22 CFR**Proposed Rules:**

1305 35134

33 CFR

3 35073
20 35073
64 35073
67 35073
80 35073
82 35073
83 35073
84 35073
100 (2 documents) 35093,
35094
104 35073
105 35073
109 35073
110 35073
115 35073
117 (2 documents) 35073,
35094
120 35073
133 35073
135 35073
136 35073
137 35073
138 35073
151 35073
155 35073
157 35073
159 35073
161 35073
162 35073
164 35073
165 (5 documents) 35073,
35095, 35097, 35099
174 35073
181 35073
Proposed Rules:
165 (2 documents) 35136,
35138

38 CFR**Proposed Rules:**

4 35140

40 CFR

52 (3 documents) 35101,
35104, 35106
180 (3 documents) 35109,
35115, 35120

Proposed Rules:

52 (4 documents) 35148,
35149, 35153

42 CFR

424 35122

Proposed Rules:

409 35270
447 35155
484 35270

46 CFR

4 35073
28 35073
31 35073
39 35073
44 35073
50 35073
58 35073
63 35073
69 35073
71 35073
107 35073
110 35073
111 35073
116 35073
120 35073
127 35073
153 35073
154 35073
161 35073
162 35073
170 35073
177 35073
182 35073
189 35073

50 CFR

679 (2 documents) 35125,
25126

Rules and Regulations

Federal Register

Vol. 82, No. 144

Friday, July 28, 2017

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

The Code of Federal Regulations is sold by the Superintendent of Documents.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2015–3324; Special Conditions No. 25–650–SC]

Special Conditions: L–3 Communications Integrated Systems; Boeing Model 747–8 Series Airplanes, Large Non-Structural Glass in the Passenger Compartment

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; correction.

SUMMARY: This document corrects an error that appeared in Docket No. FAA–2015–3324, Special Conditions No. 25–650–SC, which was published in the **Federal Register** on March 17, 2017 (82 FR 14111). This error was the inadvertent inclusion of an erroneous word in the special conditions wording of the final special conditions document.

DATES: The effective date of this correction is July 28, 2017.

FOR FURTHER INFORMATION CONTACT: Alan Sinclair, FAA, Airframe and Cabin Safety, ANM–115, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington, 98057–3356; telephone 425–227–2195; facsimile 425–227–1320; email alan.sinclair@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

On March 17, 2017, the **Federal Register** published a document designated as Docket No. FAA–2015–3324, Final Special Conditions No. 25–650–SC (82 FR 14111). The document issued special conditions pertaining to the installation of large non-structural glass panels in the cabin area of an executive interior occupied by

passengers and crew. As published, the document contained an error in that an inadvertent erroneous word was included in the final special conditions portion of the document.

Correction

In the final special conditions document (FR Doc. 2017–05330, Filed 3–16–17; 8:45 a.m.), published on March 17, 2017 (82 FR 14111), make the following correction.

On page 14112, third column, under special condition no. 1. *Material Fragmentation*, remove the word “all” from line 7 of the paragraph.

Issued in Renton, Washington, on July 19, 2017.

Victor Wicklund,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2017–15919 Filed 7–27–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2017–0237; Airspace Docket No. 16–ANM–10]

Establishment of Class E Airspace, Del Norte, CO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E airspace extending upward from 700 feet above the surface at Astronaut Kent Rominger Airport, Del Norte, CO, to support the development of instrument flight rules (IFR) operations under standard instrument approach and departure procedures at the airport, for the safety and management of aircraft within the National Airspace System.

DATES: Effective 0901 UTC, October 12, 2017. 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 7400.11A, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at <http://www.faa.gov/>

[air_traffic/publications/](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 this material at NARA, call (202) 741–6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Tom Clark, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA 98057; telephone (425) 203–4511.

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 establishes Class E airspace at Astronaut Kent Rominger Airport, Del Norte, CO, to support the development of IFR operations in standard instrument approach procedures at the airport.

History

On April 20, 2017, the FAA published in the **Federal Register** (82 FR 18598) Docket FAA–2017–0237 a notice of proposed rulemaking to establish Class E airspace extending upward from 700 feet above the surface at Astronaut Kent Rominger Airport, Del Norte, CO. 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 paragraph 6005 of FAA Order 7400.11A, dated August 3, 2016, and effective September 15, 2016, which is incorporated by reference in 14 CFR part 71.1. The Class E airspace designation 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 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016. FAA Order 7400.11A is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11A 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 establishes Class E airspace extending upward from 700 feet above the surface at Astronaut Kent Rominger Airport, Del Norte, CO, within a 7.3-mile radius of Astronaut Kent Rominger Airport beginning at the 045° bearing from the airport clockwise to the 265° bearing from the airport, thence directly to the point of beginning. This airspace is necessary to support IFR operations in standard instrument approach and departure procedures at the airport.

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, will 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 5–6.5a. 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 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016, is amended as follows:

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

* * * * *

ANM CO E5 Del Norte, CO [New]

Astronaut Kent Rominger Airport, CO
(Lat. 37°42'50" N., long. 106°21'07" W.)

That airspace extending upward from 700 feet above the surface within a 7.3-mile radius of Astronaut Kent Rominger Airport beginning at the 045° bearing from the airport clockwise to the 265° bearing from the airport, thence directly to the point of beginning.

Issued in Seattle, Washington, on July 17, 2017.

Sam S.L. Shrimpton,

Acting Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2017–15619 Filed 7–27–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2016–9474; Airspace Docket No. 16–AWP–24]

Amendment of Class E Airspace Areas, and Establishment of Class E Airspace; Bishop, CA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies Class E surface area airspace, and Class E airspace extending upward from 700 feet above the surface at Bishop Airport (formerly Eastern Sierra Regional Airport), Bishop, CA. This action also establishes Class E surface area airspace designated as an extension at this airport. After a review, the FAA found these modifications are necessary for the safety and management of Instrument Flight Rules aircraft operations at the airport.

DATES: Effective 0901 UTC, October 12, 2017. 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 7400.11A, Airspace Designations and Reporting Points, and subsequent amendments can be viewed on line 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 this material at NARA, call (202) 741–6030, or go to http://www.archives.gov/federal-register/code_of_federal-regulations/ibr_locations.html.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Tom Clark, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA 98057; telephone (425) 203–4511.

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 at Bishop Airport, Bishop, CA, to support standard instrument approach procedures for IFR operations at the airport.

History

On March 23, 2017, the FAA published a notice of proposed rulemaking (NPRM) in the **Federal Register** (82 FR 14841) Docket No. FAA-2016-9474 to modify Class E surface area airspace, and Class E airspace extending upward from 700 feet above the surface, and establish Class E surface area airspace designated as an extension at Bishop Airport, Bishop, CA. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

After publication of the NPRM, the FAA determined the proposed reduction to Class E airspace upward from 1,200 feet included an error in the proposed legal description. The airspace area should be reduced northwest of the airport, but should continue to extend to 18.7 miles southeast of the airport, instead of reduced to 10.4 miles southeast, as stated in the NPRM. This action corrects the error.

Class E airspace designations are published in paragraph 6002, 6004 and 6005, respectively, of FAA Order 7400.11A dated August 3, 2016, and effective September 15, 2016, 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 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016. FAA Order 7400.11A is publicly available as

listed in the **ADDRESSES** section of this document. FAA Order 7400.11A lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

The FAA is amending Title 14 Code of Federal Regulations (14 CFR) part 71 by modifying Class E surface area airspace, modifying Class E airspace extending upward from 700 feet above the surface, and establishing Class E surface area airspace designated as an extension, at Bishop Airport, Bishop, CA.

Class E surface area airspace is modified to within a 5-mile radius (from a 4.2-mile radius) of Bishop Airport, with 2 segments extending from the 5-mile radius to 6.9 miles northwest of the airport, and 9.6 miles north-northwest of the airport, respectively.

Class E airspace extending upward from 700 feet above the surface is modified to within a 6.7-mile radius of Bishop Airport, with a 7.2-mile wide segment extending to 11.5 miles northeast of the airport. Also, the Class E airspace extending upward from 1,200 feet above the surface is reduced northwest of the airport, as this area largely duplicates the Coaldale, NV, Class E en route airspace area, but retains a small area southeast of the airport to support current IFR operations. Additionally, Class E airspace extending upward from 12,500 feet MSL is removed, as this airspace supports no current IFR operations.

These airspace modifications are necessary for the safety and management of IFR operations in standard instrument approach and departure procedures at the airport. Additionally, the airport name is changed from Eastern Sierra Regional Airport to Bishop Airport, to be in concert with the FAA's aeronautical database.

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 5-6.5a. 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 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016, is amended as follows:

Paragraph 6002 Class E Airspace Areas Designated as a Surface Area.

* * * * *

AWP CA E2 Bishop, CA [Modified]

Bishop Airport, CA
(Lat. 37°22'23" N., long. 118°21'49" W.)
Within a 5-mile radius of Bishop Airport.

Paragraph 6004 Class E Airspace Areas Designated as an Extension to a Class D or Class E Surface Area.

* * * * *

AWP CA E4 Bishop, CA [New]

Bishop Airport, CA
(Lat. 37°22'23" N., long. 118°21'49" W.)

That airspace extending upward from the surface within 1.2 miles each side of a 315° bearing from Bishop Airport extending from the 5-mile radius of the airport to 6.9 miles northwest of the airport, and within 1.2 miles each side of a 337° bearing from the airport

extending from the 5-mile radius of the airport to 9.6 miles northwest of the airport.

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

* * * * *

AWP CA E5 Bishop, CA [Modified]

Bishop Airport, CA
(Lat. 37°22'23" N., long. 118°21'49" W.)

That airspace upward from 700 feet above the surface within a 6.7-mile radius of Bishop Airport, and within 4 miles west and 3.2 miles east of a 337° bearing from the airport extending from the 6.7-mile radius of the airport to 15.2 miles northwest of the airport. That airspace upward from 1,200 feet above the surface within 3 miles southwest and 11.5 miles northeast of a 157° bearing from Bishop Airport extending from the airport to 18.7 miles southeast of the airport.

Issued in Seattle, Washington, on July 19, 2017.

Sam S.L. Shrimpton,

Acting Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2017-15867 Filed 7-27-17; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2017-0258; Airspace Docket No. 16-AWP-15]

Amendment of Class E Airspace, Colorado City, AZ

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies Class E airspace extending upward from 700 feet above the surface at Colorado City Municipal Airport, Colorado City, AZ, to support the implementation of new Area Navigation (RNAV) Global Positioning System (GPS) standard instrument approach procedures for instrument flight rules (IFR) operations at the airport. In addition, it removes the Class E airspace area extending upward from 1,200 feet. Also, this action updates the geographic coordinates of the airport to match the FAA's current aeronautical database. This action enhances the safety and management of controlled airspace within the national airspace system.

DATES: Effective 0901 UTC, October 12, 2017. 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 7400.11A, 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 this material at NARA, call (202) 741-6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Tom Clark, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA 98057; telephone (425) 203-4511.

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 modifies Class E airspace extending upward from 700 feet above the surface at Colorado City Municipal Airport, Colorado City, AZ, to support the implementation of new Area Navigation (RNAV) Global Positioning System (GPS) standard instrument approach procedures for instrument flight rules (IFR) operations at the airport.

History

On April 27, 2017, the FAA published a notice of proposed rulemaking in the **Federal Register** (82 FR 19329) Docket No. FAA-2017-0258, to modify Class E airspace extending upward from 700 and 1,200 feet above the surface at Colorado City Municipal Airport,

Colorado City, AZ. 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 paragraph 6005 of FAA Order 7400.11A, dated August 3, 2016, and effective September 15, 2016, which is incorporated by reference in 14 CFR part 71.1. The Class E airspace designation 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 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016. FAA Order 7400.11A is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11A 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 Class E airspace extending upward from 700 feet above the surface at Colorado City Municipal Airport, Colorado City, AZ. The airspace is expanded from the 6.5-mile radius of the airport to 7.8 miles west and 2 miles east of the 163° (from 173°) bearing from the airport to 16 miles (from 12 miles) south of the airport to contain the NDB-A procedure turn. Also, a segment is added from the 6.5-mile radius of the airport extending to 15.1 miles southeast of the airport to support a new RNAV GPS RWY 29 instrument approach procedure for IFR operations at the airport.

Additionally, the Class E airspace area extending upward from 1,200 feet is removed as there is sufficient 1,200-foot airspace provided by St. George Class E airspace extending from 700 feet above the surface and Grand Canyon Class E en route airspace.

Also, this action updates the geographic coordinates of the airport to lat. 36°57'36" N., long. 113°00'50" W. (from lat. 36°57'08" N., long. 113°00'59" W.), to match the FAA's current aeronautical database. This action ensures the safety and management of controlled airspace within the national airspace system as it transitions from ground based navigation aids to satellite-based Global Navigation Satellite System for navigation.

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, will 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 5–6.5a. 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 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016, is amended as follows:

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

* * * * *

AWP AZ E5 Colorado City, AZ [Modified]

Colorado City Municipal Airport, AZ
(Lat. 36°57′36″ N., long. 113°00′50″ W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of the Colorado City Municipal Airport, and within 7.8 miles west and 4.2 miles east of a 163° bearing extending from the airport to 16 miles south of the airport, and within 2 miles each side of a 123° bearing from the airport extending to 15.1 miles southeast of the airport.

Issued in Seattle, Washington, on July 19, 2017.

Sam S.L. Shrimpton,

Acting Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2017–15866 Filed 7–27–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2017–0046; Airspace Docket No. 17–AWP–3]

Establishment of Class E Airspace, Willits, CA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E airspace extending upward from 700 feet above the surface at Frank R. Howard Memorial Hospital Heliport, Willits, CA, to support the development of instrument flight rules (IFR) operations under standard instrument approach and departure procedures at the heliport, for the safety and management of aircraft within the National Airspace System.

DATES: Effective 0901 UTC, October 12, 2017. 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 7400.11A, 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 this material at NARA, call (202) 741–6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Tom Clark, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA 98057; telephone (425) 203–4511.

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 establishes Class E airspace at Frank R. Howard Memorial Hospital Heliport, Willits, CA, to support the development of IFR operations in standard instrument approach procedures at the heliport.

History

On March 28, 2017, the FAA published in the **Federal Register** (82 FR 15304) Docket FAA–2017–0046 a notice of proposed rulemaking to establish Class E airspace extending upward from 700 feet above the surface at Frank R. Howard Memorial Hospital Heliport, Willits, CA. 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 paragraph 6005 of FAA Order 7400.11A, dated August 3, 2016, and effective September 15, 2016, which is incorporated by reference in 14 CFR part 71.1. The Class E airspace designation 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 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016. FAA Order 7400.11A is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11A 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 establishes Class E airspace extending upward from 700 feet above the surface at Frank R. Howard Memorial Hospital Heliport, Willits, CA, within a 2.5-mile radius of the heliport, and within 2.5 miles each side of the 166° bearing from the heliport to 6.7 miles southeast of the heliport, and within 1.5 miles each side of the 360° bearing from the heliport to 10.5 miles north of the heliport. This airspace is necessary to support IFR operations in new standard instrument approach and departure procedures at the airport.

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, will 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 5–6.5a. 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 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016, is amended as follows:

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

* * * * *

AWP CA E5 Willits, CA [New]

Frank R. Howard Memorial Hospital Heliport, CA

(Lat. 39°23′21″ N., long. 123°20′21″ W.)

That airspace upward from 700 feet above the surface within a 2.5-mile radius of Frank R. Howard Memorial Hospital Heliport, and within 2.5 miles each side of the 166° bearing from the heliport to 6.7 miles southeast of the heliport, and within 1.5 miles each side of the 360° bearing from the heliport to 10.5 miles north of the heliport.

Issued in Seattle, Washington, on July 19, 2017.

Sam S.L. Shrimpton,

Acting Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2017–15869 Filed 7–27–17; 8:45 am]

BILLING CODE 4910–13–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 232

[Release Nos. 33–10385; 34–81080; 39–2517; IC–32724]

Adoption of Updated EDGAR Filer Manual

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: The Securities and Exchange Commission (“the Commission”) is adopting revisions to the Electronic Data Gathering, Analysis, and Retrieval System (“EDGAR”) Filer Manual and related rules to reflect updates to the EDGAR system. The updates are being made primarily to reflect amendments made to several forms under the Securities Act of 1933 (“Securities Act”) and the Securities Exchange Act of 1934 (“Exchange Act”) to effectuate inflation adjustments and other technical amendments required under Titles I and III of the Jumpstart Our Business Startups (“JOBS”) Act; support recent updates to Form C and Form D; includes instructions for hyperlinking to exhibits included with certain Securities Act and Exchange Act forms and makes certain corrective changes to previously revised sections. The revised EDGAR Filer Manual also announces updates to the technical specifications for the ABS–EE schema and terminates support for US–GAAP–2015, EXCH–2015, CURRENCY–2014, and COUNTRY–2013 taxonomies. The EDGAR system is scheduled to be upgraded on July 17, 2017.

DATES: Effective July 28, 2017. The incorporation by reference of the EDGAR Filer Manual is approved by the Director of the Federal Register as of July 28, 2017.

FOR FURTHER INFORMATION CONTACT: In the Division of Corporation Finance, for questions concerning Forms ABS–EE, ABS–15G, C, D, S–1, S–3, S–4, S–8, S–11, F–1, F–3, F–4, 8–K, 10, 10–D, 10–K, 10–Q, 20–F, and 40–F, contact Heather Mackintosh at (202) 551–8111; in the Division of Trading and Markets, for questions concerning Forms 17–H and X–17A–5, contact Kathy Bateman at (202) 551–4345; in the Office of Investment Management, for questions concerning Forms 1–E, 2–E, N–1A, N–23C–2, N–23C3, 40–APP, and 40–17G, contact Heather Fernandez at (202) 551–6708; and in the Division of Economic and Risk Analysis, for questions concerning taxonomies and eXtensible Business Reporting Language (XBRL), contact Brian Hankin at (202) 551–8497.

SUPPLEMENTARY INFORMATION: We are adopting an updated EDGAR Filer Manual, Volume I and Volume II. The Filer Manual describes the technical formatting requirements for the preparation and submission of electronic filings through the EDGAR system.¹ It also describes the

¹ We originally adopted the Filer Manual on April 1, 1993, with an effective date of April 26, 1993. Release No. 33–6986 (April 1, 1993) [58 FR 18638]. We implemented the most recent update to the Filer Manual on March 13, 2017. See Release No. 33–10324 (March 31, 2017) [82 FR 15993].

requirements for filing using EDGARLink Online and the Online Forms/XML Web site.

The revisions to the Filer Manual reflect changes within Volume I entitled EDGAR Filer Manual, Volume I: "General Information," Version 28 (July 2017) and Volume II entitled EDGAR Filer Manual, Volume II: "EDGAR Filing," Version 42 (July 2017). The updated manual will be incorporated by reference into the Code of Federal Regulations.

The Filer Manual contains all the technical specifications for filers to submit filings using the EDGAR system. Filers must comply with the applicable provisions of the Filer Manual in order to assure the timely acceptance and processing of filings made in electronic format.² Filers may consult the Filer Manual in conjunction with our rules governing mandated electronic filing when preparing documents for electronic submission.³

The EDGAR system will be upgraded to Release 17.2 on July 17, 2017 and will introduce the following changes:

Effective September 1, 2017, large accelerated and accelerated filers filing Forms S-1, S-3, S-4, S-8, S-11, F-1, F-3, F-4, F-10, SF-1, and SF-3 under the Securities Act and Forms 10, 10-K, 10-Q, 8-K, 20-F, and 10-D under the Exchange Act will be required to submit these forms in HTML and include a hyperlink to each exhibit listed in the exhibit index of these filings, including exhibits that are incorporated by reference.⁴ Instructions for hyperlinking to an exhibit submitted with a previous submission, or an exhibit that is being filed concurrently with the submission, have been included in Chapter 5 of Volume II of the EDGAR Filer Manual. Instructions for using HTML Styles to indicate the location of the Exhibit Links and the Summary Section have also been included in Chapter 5 of Volume II of the EDGAR Filer Manual.

² See Rule 301 of Regulation S-T (17 CFR 232.301).

³ See Release No. 33-10324 in which we implemented revisions to reflect EDGAR Release 17.1. For additional history of EDGAR Filer Manual revisions, please see the citations therein.

⁴ Non-accelerated filers and smaller reporting companies that submit filings in ASCII will not need to comply with these requirements until September 1, 2018. The compliance date for any Form 10-D filing that will require a hyperlink to an exhibit filed with Form ABS-EE will be delayed until SEC staff completes programming changes to EDGAR. These changes will allow Form 10-D filers to include the Form 10-D and Form ABS-EE in a single submission so that the required exhibit hyperlinks can be created at the time the Form 10-D is filed. The Commission will publish a notice in the *Federal Register* and on the Commission Web site announcing the compliance date for those Form 10-D filings.

Submission form types D and D/A will be updated to remove the reference to "Rule 505" in Item 6: Federal Exemption(s) and Exclusion(s) Claimed. The "Terms of Submission" in the Signature and Submission screen will be updated to replace the references to "relying on Regulation D" and "Rule 505(b)(2)(iii)" with "relying on Rule 504 or Rule 506" and "Rule 504(b)(3)," respectively. The Total Offering Amount in "Item 13: Offering and Sales Amounts" will increase from a maximum of \$1,000,000 to \$5,000,000 if any "Rule 504" item is selected on submission form types D and D/A. Corresponding changes will be made to Chapter 8 and Appendix A of the EDGAR Filer Manual.

In Release No. 33-10332 (March 31, 2017) [82 FR 17545], the Commission adopted rule changes to effectuate inflation adjustments and other technical amendments required under Titles I and III of the JOBS Act. The technical changes included revisions to Commission forms so that registrants can designate whether they are an Emerging Growth Company (EGC) and inform the Commission as to whether they have elected not to use the extended transition period for EGCs to comply with any new or revised financial accounting standards. The following EDGARLink Online submission form types will be revised to reflect the two fields: S-1, S-1/A, S-3, S-3/A, S-4, S-4/A, S-8, S-11, S-11/A, F-1, F-1/A, F-3, F-3/A, F-4, F-4/A, 10-12B, 10-12B/A, 10-12G, 10-12G/A, 8-K, 8-K/A, 8-K12B, 8-K12B/A, 8-K12G3, 8-K12G3/A, 8-K15D5, 8-K15D5/A, 10-Q, 10-Q/A, 10-QT, 10-QT/A, 10-K, 10-K/A, 10-KT, 10-KT/A, 20-F, 20-F/A, 20FR12B, 20FR12B/A, 20FR12G, 20FR12G/A, 40-F, 40-F/A, 40FR12B, 40FR12B/A, 40FR12G, and 40FR12G/A. Corresponding changes will be made to Chapter 7 of the EDGAR Filer Manual. In addition, submission form types C and C/A will be updated to increase the maximum limit of the "Target Offering Amount" and "Maximum Offering Amount" fields to \$1,070,000. Corresponding changes will be made to Chapter 8 of the EDGAR Filer Manual.

EDGAR will be updated so that broker-dealers filing submission form type 17HACON must indicate whether or not the submission is for a full year. Submission form type 17HACON will require broker-dealers to attach an "ORGCHART" document to confidential annual 17-H reports on submission form type 17HACON even if the field "No material changes have occurred since last filed" is selected. Corresponding changes will be made to

Chapter 8 of Volume II of the EDGAR Filer Manual.

An Instructions menu icon will be added to the filer interface in the top-right corner for submission form types X-17A-5 and X-17A-5/A, which provides instructions on how to file broker-dealer annual reports through EDGAR. Corresponding changes will be made to Chapter 8 of Volume II of the EDGAR Filer Manual.

Filers will no longer have to submit form type N-1A using "dummy" Series and Classes (Contracts) and will instead be able to register via submission form type N-1A using their existing Series and Classes (Contracts). Corresponding Changes will be made to Chapter 7 of Volume II of the EDGAR Filer Manual.

Clarifying changes to Chapter 8 of Volume II of the EDGAR Filer Manual will be added to specify that, when Transfer Agent form submissions created using the filer interface, filers are limited to a maximum of 100 document attachments. Also, the revision clarifies that the maximum size of a Transfer Agent submission, including all attached documents, may not exceed 200 MB.

Chapter 5, Section 5.2.5.9 will be revised to remove duplicate HTML tags. Chapter 6, section 6.12.7 will be revised to clarify that start/end labels should not be used on duration-type facts. Chapters 5 and 6 will be revised to include clarifying changes instructions for data tagging and labeling.

The ABS-EE schema will be updated with the following changes:

- RMBS, 1(m)(21)(xi) postModification ARMPaymentRecastFrequency will be changed from decimal format to integer format, with a maximum length of eight digits.
- The maximum integer length will increase from two digits to eight digits for the following Asset Class Items:
 - Item 1(c)(29)(iv), initialFixedRatePeriod HybridARMNumber;
 - Item 1(c)(29)(xxi), HELOCDrawNumber;
 - Item 1(m)(21)(iv), postModification InterestResetNumber;
 - Item 1(m)(21)(xx), postModification ARM InterestRateTeaserNumber;
 - Item 1(m)(21)(xxi), postModification ARMPaymentTeaserNumber;
 - Item 1(m)(22)(i), postModification InterestOnlyTermNumber;
 - Item 3(c)(9), originalInterestOnlyTerm Number;
 - Item 3(c)(12), gracePeriodNumber;
 - Item 3(j)(2), paymentExtendedNumber;
 - Item 4(c)(8), gracePeriod; and
 - Item 4(j)(2), leaseExtended.

For more information, see the updated EDGAR ABS XML Technical Specification document available on the SEC's Public Web site (<https://www.sec.gov/info/edgar/tech-specs>).

EDGAR will no longer provide support for the US-GAAP-2015, EXCH-2015, CURRENCY-2014, and COUNTRY-2013 taxonomies. Please see https://www.sec.gov/info/edgar/edgar_taxonomies.shtml for a complete list of supported standard taxonomies.

Along with the adoption of the Filer Manual, we are amending Rule 301 of Regulation S-T to provide for the incorporation by reference into the Code of Federal Regulations of these revisions. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

The updated EDGAR Filer Manual will be available for Web site viewing and printing; the address for the Filer Manual is <https://www.sec.gov/info/edgar/edmanuals.htm>. You may also obtain paper copies of the EDGAR Filer Manual from the following address: Public Reference Room, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m.

Since the Filer Manual and the corresponding rule changes relate solely to agency procedures or practice, publication for notice and comment is not required under the Administrative Procedure Act ("APA").⁵ It follows that the requirements of the Regulatory Flexibility Act⁶ do not apply.

The effective date for the updated Filer Manual and the rule amendments is July 28, 2017. In accordance with the APA,⁷ we find that there is good cause to establish an effective date less than 30 days after publication of these rules. The EDGAR system upgrade to Release 17.2 is scheduled to become available on July 17, 2017. The Commission believes that establishing an effective date less than 30 days after publication of these rules is necessary to coordinate the effectiveness of the updated Filer Manual with these system upgrades.

Statutory Basis

We are adopting the amendments to Regulation S-T under Sections 6, 7, 8, 10, and 19(a) of the Securities Act of 1933,⁸ Sections 3, 12, 13, 14, 15, 23, and 35A of the Securities Exchange Act of 1934,⁹ Section 319 of the Trust Indenture Act of 1939,¹⁰ and Sections 8, 30, 31, and 38 of the Investment Company Act of 1940.¹¹

List of Subjects in 17 CFR Part 232

Incorporation by reference, Reporting and recordkeeping requirements, Securities.

Text of the Amendment

In accordance with the foregoing, title 17, chapter II of the Code of Federal Regulations is amended as follows:

PART 232—REGULATION S-T—GENERAL RULES AND REGULATIONS FOR ELECTRONIC FILINGS

■ 1. The authority citation for part 232 continues to read in part as follows:

Authority: 15 U.S.C. 77c, 77f, 77g, 77h, 77j, 77s(a), 77z-3, 77sss(a), 78c(b), 78l, 78m, 78n, 78o(d), 78w(a), 78ll, 80a-6(c), 80a-8, 80a-29, 80a-30, 80a-37, and 7201 *et seq.*; and 18 U.S.C. 1350, unless otherwise noted.

* * * * *

■ 2. Section 232.301 is revised to read as follows:

§ 232.301 EDGAR Filer Manual.

Filers must prepare electronic filings in the manner prescribed by the EDGAR Filer Manual, promulgated by the Commission, which sets out the technical formatting requirements for electronic submissions. The requirements for becoming an EDGAR Filer and updating company data are set forth in the updated EDGAR Filer Manual, Volume I: "General Information," Version 28 (July 2017). The requirements for filing on EDGAR are set forth in the updated EDGAR Filer Manual, Volume II: "EDGAR Filing," Version 42 (July 2017). All of these provisions have been incorporated by reference into the Code of Federal Regulations, which action was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You must comply with these requirements in order for documents to be timely received and accepted. The EDGAR Filer Manual is available for Web site viewing and printing; the address for the Filer Manual is <https://www.sec.gov/info/edgar/edmanuals.htm>. You can obtain paper copies of the EDGAR Filer Manual from the following address: Public Reference Room, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. You can also inspect the document at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

Dated: July 6, 2017.

By the Commission.

Brent J. Fields,
Secretary.

[FR Doc. 2017-15862 Filed 7-27-17; 8:45 am]

BILLING CODE 8011-01-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

DEPARTMENT OF THE TREASURY

19 CFR Parts 159 and 181

[CBP Dec. 17-08]

Technical Corrections to U.S. Customs and Border Protection Regulations

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security; Department of the Treasury.

ACTION: Final rule.

SUMMARY: U.S. Customs and Border Protection (CBP) periodically reviews its regulations to ensure that they are current, correct, and consistent. Through this review process, CBP discovered some discrepancies. This document amends certain sections of title 19 of the Code of Federal Regulations to remedy these discrepancies.

DATES: The final rule is effective July 28, 2017.

FOR FURTHER INFORMATION CONTACT: Grace A. Kim, Regulations and Rulings, Office of Trade, (202) 325-7941.

SUPPLEMENTARY INFORMATION:

Background

It is the policy of U.S. Customs and Border Protection (CBP) to periodically review title 19 of the Code of Federal Regulations (19 CFR) to ensure that it is accurate and up-to-date so that the importing and general public is aware of CBP programs, requirements, and procedures regarding import-related activities. As part of this review policy, CBP has determined that certain corrections to 19 CFR parts 159 and 181 are necessary.

Discussion of Changes

Part 159

Section 159.58 (19 CFR 159.58) concerns the suspension of liquidation by CBP when there are antidumping and countervailing duty determinations. The references to part 353 of title 19 CFR in 19 CFR 159.58(a) and to part 355 of title 19 CFR in 19 CFR 159.58(b) are incorrect. On May 19, 1997, the U.S.

⁵ 5 U.S.C. 553(b)(A).

⁶ 5 U.S.C. 601-612.

⁷ 5 U.S.C. 553(d)(3).

⁸ 15 U.S.C. 77f, 77g, 77h, 77j, and 77s(a).

⁹ 15 U.S.C. 78c, 78l, 78m, 78n, 78o, 78w, and 78ll.

¹⁰ 15 U.S.C. 77sss.

¹¹ 15 U.S.C. 80a-8, 80a-29, 80a-30, and 80a-37.

Department of Commerce revised its regulations on antidumping and countervailing duty proceedings to conform to the Uruguay Round Agreements Act (62 FR 27296) (May 19, 1997) which resulted in a new part 351 and the deletion of parts 353 and 355. Accordingly, this document makes conforming changes to §§ 159.58(a) and 159.58(b) to reflect this revision.

Part 181

Subpart D of Part 181 of title 19 deals with post-importation duty refund claims under the North American Free Trade Agreement (NAFTA). Section 181.33(d)(1) lists instances wherein a port director may deny a post-importation duty refund claim for preferential tariff treatment for imported goods under the NAFTA, and it references § 181.32(b)(3) in the context of the validity of a Certificate of Origin. This is not the correct reference. The proper reference should be to § 181.32(b)(2), which references the requirement to file a Certificate of Origin with respect to the imported goods. Accordingly, this document makes changes to § 181.33(d)(1) to reference § 181.32(b)(2) instead of § 181.32(b)(3).

Inapplicability of Notice and Delayed Effective Date

As the technical corrections set forth in this document merely conform to existing law and regulation, CBP finds that good cause exists for dispensing with notice and public procedure as unnecessary under 5 U.S.C. 553(b)(B). For this same reason, pursuant to 5 U.S.C. 553(d)(3), CBP finds that good cause exists for dispensing with the requirement for a delayed effective date.

Regulatory Flexibility Act

Because this document is not subject to the notice and public procedure requirements of 5 U.S.C. 553, it is not subject to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Executive Order 12866

These amendments do not meet the criteria for a “significant regulatory action” as specified in Executive Order 12866, as supplemented by Executive Order 13563.

Signing Authority

This document is limited to technical corrections of the CBP regulations. Accordingly, it is being signed under the authority of 19 CFR 0.1(b)(1).

List of Subjects

19 CFR Part 159

Alcohol and alcohol beverages, Antidumping (Liquidation of duties), Cigars and cigarettes, Computer technology, Countervailing duties (Liquidation of duties), Customs duties and inspection, Discriminating duties, Entry procedures, Foreign currencies, Import, Liquidation of entries for merchandise, Suspension of liquidation pending disposition of American manufacturer's cause of action, Value content.

19 CFR Part 181

Administrative practice and procedure, Canada, Customs duties and inspection, Exports, Imports, Mexico, Reporting and recordkeeping requirements, Trade agreements (North American Free-Trade Agreements).

Amendments to the Regulations

For the reasons set forth above, parts 159 and 181 of the CBP regulations (19 CFR parts 159 and 181) are amended as set forth below.

PART 159—LIQUIDATION OF DUTIES

- 1. The general authority citation for part 159 continues to read as follows:

Authority: 19 U.S.C. 66, 1500, 1504, 1624.

* * * * *

§ 159.58 [Amended]

- 2. Section 159.58 is amended:
 - a. In paragraph (a) by removing the term “part 353” and adding in its place the term “part 351”; and
 - b. In paragraph (b) by removing the term “part 355” and adding in its place the term “part 351”.

PART 181—NORTH AMERICAN FREE TRADE AGREEMENT

- 3. The authority citation for part 181 continues to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States (HTSUS)), 1624, 3314.

Subpart D of part 181 also issued under 19 U.S.C. 1520(d).

§ 181.33 [Amended]

- 4. Section 181.33(d)(1) is amended by removing the citation “§ 181.32(b)(3)” and adding in its place the citation “§ 181.32(b)(2)”.

Dated: July 24, 2017.

Kevin K. McAleenan,

Acting Commissioner, U.S. Customs and Border Protection.

[FR Doc. 2017-15888 Filed 7-27-17; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA-2017-N-1620]

Medical Devices; Cardiovascular Devices; Classification of the Adjunctive Cardiovascular Status Indicator

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the adjunctive cardiovascular status indicator into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the adjunctive cardiovascular status indicator's classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective July 28, 2017. The classification was applicable on December 21, 2016.

FOR FURTHER INFORMATION CONTACT:

Nathalie Yarkony, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1254, Silver Spring, MD 20993-0002, 301-796-1235, nathalie.yarkony@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, also known as De Novo classification, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of “low-moderate risk” or that general controls would be inadequate to control the risks

and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA shall classify the device by written order within 120 days. This classification will be the initial classification of the device.

On May 24, 2016, Flashback Technologies submitted a request for classification of the CipherOx CRI Tablet under section 513(f)(2) of the FD&C Act.

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1). FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on December 21, 2016, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding § 870.2200.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for an adjunctive cardiovascular status indicator will need to comply with the special controls named in this final order. A De Novo classification decreases regulatory burdens. When FDA classifies a device type as class I or II via the De Novo pathway, other manufacturers do not have to submit a De Novo request or premarket approval application in order to market the same type of device, unless the device has a new intended use or technological characteristics that raise different questions of safety or effectiveness. Instead, manufacturers can use the less burdensome 510(k) pathway, when necessary, to market their device, and the device that was the subject of the original De Novo classification can serve as a predicate device for additional 510(k)s from other manufacturers.

The device is assigned the generic name adjunctive cardiovascular status indicator, and it is identified as a prescription device based on sensor technology for the measurement of a physical parameter(s). This device is intended for adjunctive use with other physical vital sign parameters and patient information and is not intended to independently direct therapy.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1:

TABLE 1—ADJUNCTIVE CARDIOVASCULAR STATUS INDICATOR RISKS AND MITIGATION MEASURES

Identified risk	Mitigation measures
Delayed or incorrect treatment due to erroneous output as a result of software malfunction or algorithm error.	Software verification, validation, and hazard analysis. Non-clinical performance testing. Clinical performance testing. Labeling.
Delayed or incorrect treatment due to user misinterpretation	Usability assessment. Labeling.

FDA believes that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness.

Adjunctive cardiovascular status indicators are not safe for use except under the supervision of a practitioner licensed by law to direct the use of the device. As such, the device is a prescription device and must satisfy prescription labeling requirements (see 21 CFR 801.109 *Prescription devices*).

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification

requirements under section 510(k), if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA believes premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, is planning to exempt the device from the premarket notification requirements under section 510(m) of the FD&C Act. Once finalized, persons who intend to market this device type need not submit a 510(k) premarket notification containing information on

the adjunctive cardiovascular status indicator prior to marketing the device.

II. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Paperwork Reduction Act of 1995

This final administrative order establishes special controls that refer to previously approved collections of

information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801, regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 870

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 870 is amended as follows:

PART 870—CARDIOVASCULAR DEVICES

■ 1. The authority citation for part 870 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 870.2200 to subpart C to read as follows:

§ 870.2200 Adjunctive cardiovascular status indicator.

(a) *Identification.* The adjunctive cardiovascular status indicator is a prescription device based on sensor technology for the measurement of a physical parameter(s). This device is intended for adjunctive use with other physical vital sign parameters and patient information and is not intended to independently direct therapy.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Software description, verification, and validation based on comprehensive hazard analysis must be provided, including:

(i) Full characterization of technical parameters of the software, including any proprietary algorithm(s);

(ii) Description of the expected impact of all applicable sensor acquisition hardware characteristics on performance and any associated hardware specifications;

(iii) Specification of acceptable incoming sensor data quality control measures; and

(iv) Mitigation of impact of user error or failure of any subsystem components (signal detection and analysis, data display, and storage) on accuracy of patient reports.

(2) Scientific justification for the validity of the status indicator

algorithm(s) must be provided. Verification of algorithm calculations and validation testing of the algorithm using a data set separate from the training data must demonstrate the validity of modeling.

(3) Usability assessment must be provided to demonstrate that risk of misinterpretation of the status indicator is appropriately mitigated.

(4) Clinical data must be provided in support of the intended use and include the following:

(i) Output measure(s) must be compared to an acceptable reference method to demonstrate that the output measure(s) represent(s) the predictive measure(s) that the device provides in an accurate and reproducible manner;

(ii) The data set must be representative of the intended use population for the device. Any selection criteria or limitations of the samples must be fully described and justified;

(iii) Agreement of the measure(s) with the reference measure(s) must be assessed across the full measurement range; and

(iv) Data must be provided within the clinical validation study or using equivalent datasets to demonstrate the consistency of the output and be representative of the range of data sources and data quality likely to be encountered in the intended use population and relevant use conditions in the intended use environment.

(5) Labeling must include the following:

(i) The type of sensor data used, including specification of compatible sensors for data acquisition;

(ii) A description of what the device measures and outputs to the user;

(iii) Warnings identifying sensor reading acquisition factors that may impact measurement results;

(iv) Guidance for interpretation of the measurements, including warning(s) specifying adjunctive use of the measurements;

(v) Key assumptions made in the calculation and determination of measurements;

(vi) The measurement performance of the device for all presented parameters, with appropriate confidence intervals, and the supporting evidence for this performance; and

(vii) A detailed description of the patients studied in the clinical validation (e.g., age, gender, race/ethnicity, clinical stability) as well as procedural details of the clinical study.

Dated: July 24, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–15901 Filed 7–27–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA–2017–N–1609]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Oral Removable Palatal Space Occupying Device for Weight Management and/or Weight Loss

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or Agency) is classifying the oral removable palatal space occupying device for weight management and/or weight loss into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the oral removable palatal space occupying device for weight management and/or weight loss classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective July 28, 2017. The classification was applicable on September 26, 2016.

FOR FURTHER INFORMATION CONTACT:

Mark Antonino, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G208, Silver Spring, MD, 20993–0002, 240–402–9980, mark.antonino@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially

equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations. Section 513(f)(2) of the FD&C Act, also known as De Novo classification, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1) of the FD&C Act. Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1), the person requests a classification under section 513(f)(2) of the FD&C Act. Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of “low-moderate risk” or that general controls

would be inadequate to control the risks and special controls to mitigate the risks cannot be developed. In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA shall classify the device by written order within 120 days. This classification will be the initial classification of the device. On July 31, 2015, Scientific Intake submitted a request for classification of the Sensor Monitored Alimentary Restriction Therapy (SMART) device under section 513(f)(2) of the FD&C Act. In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1). FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device. Therefore, on September 26, 2016, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 876.5981. Following the effective date of this final classification order, any firm

submitting a premarket notification (510(k)) for an oral removable palatal space occupying device for weight management and/or weight loss will need to comply with the special controls named in this final order. A De Novo classification decreases regulatory burdens. When FDA classifies a device type as class I or II via the De Novo pathway, other manufacturers do not have to submit a De Novo request or premarket approval application to market the same type of device, unless the device has a new intended use or technological characteristics that raise different questions of safety or effectiveness. Instead, manufacturers can use the less burdensome 510(k) pathway, when necessary, to market their device, and the device that was the subject of the original De Novo classification can serve as a predicate device for additional 510(k)s from other manufacturers. The device is assigned the generic name oral removable palatal space occupying device for weight management and/or weight loss, and it is identified as a prescription device that is worn during meals to limit bite size, thereby reducing the amount of food that is consumed. The device may contain recording sensors for monitoring patient use. This classification does not include devices that are intended to treat any dental diseases or conditions. FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in Table 1.

TABLE 1—ORAL REMOVABLE PALATAL SPACE OCCUPYING DEVICE FOR WEIGHT MANAGEMENT AND/OR WEIGHT LOSS RISKS TO HEALTH AND MITIGATION MEASURES

Identified risks	Mitigation measures
Tooth Movement, Irritation, and Soreness of Mouth or Gums, including: • Improper mold making; • User error; and • Damage to material (soft edge separation) Choking or gag reflex	Non-clinical performance testing. Labeling. Training.
Adverse tissue reaction	Clinical performance testing. Labeling.
Incorrect data interpretation, including: • Hardware malfunction (sensor malfunction) Electrical shock and electrical interference with other devices	Biocompatibility evaluation.
Weight gain	Non-clinical performance testing. Labeling. Training.
	Non-clinical performance testing. Clinical performance testing. Labeling.

FDA believes that the special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness.

Oral removable palatal space occupying devices for weight management and/or weight loss are not safe for use except under the supervision of a practitioner licensed by

law to direct the use of the device. As such, the device is a prescription device and must satisfy prescription labeling requirements (see 21 CFR 801.109, *Prescription devices*).

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k), if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA believes premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, is planning to exempt the device from the premarket notification requirements under section 510(m) of the FD&C Act. Once finalized, persons who intend to market this device type need not submit a 510(k) premarket notification containing information on the oral removable palatal space occupying device for weight management and/or weight loss prior to marketing the device.

II. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801 regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 876

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 876 is amended as follows:

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

- 1. The authority citation for part 876 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

- 2. Add § 876.5981 to subpart F to read as follows:

§ 876.5981 Oral removable palatal space occupying device for weight management and/or weight loss.

(a) *Identification.* An oral removable palatal space occupying device for weight management and/or weight loss is a prescription device that is worn during meals to limit bite size, thereby reducing the amount of food that is consumed. The device may contain recording sensors for monitoring patient use. This classification does not include devices that are intended to treat any dental diseases or conditions

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The patient-contacting components of the device must be demonstrated to be biocompatible for its intended use.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions for use, as follows:

(i) Mechanical testing must demonstrate that the device performs as intended for the labeled use life and does not create forces that result in movement of teeth and damage to teeth.

(ii) Electrical safety and electromagnetic compatibility testing must demonstrate that the device performs as intended.

(iii) Software verification and validation must demonstrate that the device performs as intended.

(iv) Battery testing must demonstrate that the device battery performs as intended.

(3) Clinical performance testing must demonstrate the device performs as intended and must include an evaluation for choking.

(4) Device labeling must address the following:

(i) Patient labeling must state:
(A) The clinical benefit of weight management and/or weight loss as assessed by using percent total body weight loss;

(B) Treatment must be offered in combination with a behavioral modification program;

(C) Instructions on how to use the device as intended; and

(D) The use life of the device.

(ii) Physician labeling must state:
(A) The clinical benefit of weight management and/or weight loss as assessed by using percent total body weight loss;

(B) Treatment must be offered in combination with a behavioral modification program;

(C) Instructions on how to use the device as intended; and

(D) The use life of the device.

(5) Training must be provided to health professionals that includes

procedures for determining a patient's oral health status, instructions for making the palatal mold, and assessment of issues with the device that may require service by the manufacturer.

Dated: July 24, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–15894 Filed 7–27–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA–2017–N–1608]

Medical Devices; Neurological Devices; Classification of Cranial Motion Measurement Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or Agency) is classifying the cranial motion measurement device into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the cranial motion measurement device's classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective July 28, 2017. The classification was applicable on August 1, 2016.

FOR FURTHER INFORMATION CONTACT: Jay Gupta, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2630, Silver Spring, MD 20993–0002, 301–796–2795, jay.gupta@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require

premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, also known as De Novo classification, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1) of the FD&C Act. Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1), the person requests a classification under section 513(f)(2) of the FD&C Act. Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second

procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of “low-moderate risk” or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA shall classify the device by written order within 120 days. This classification will be the initial classification of the device.

On December 23, 2014, Jan Medical, Inc., submitted a request for classification of the BrainPulse, Model 1100, under section 513(f)(2) of the FD&C Act.

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1). FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on August 1, 2016, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 882.1630.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for a cranial motion measurement device will need to comply with the special controls named in this final order. A De Novo classification decreases regulatory burdens. When FDA classifies a device type as class I or II via the De Novo pathway, other manufacturers do not have to submit a De Novo request or premarket approval application in order to market the same type of device, unless the device has a new intended use or technological characteristics that raise different questions of safety or effectiveness. Instead, manufacturers can use the less burdensome 510(k) pathway, when necessary, to market their device, and the device that was the subject of the original De Novo classification can serve as a predicate device for additional 510(k)s from other manufacturers.

The device is assigned the generic name cranial motion measurement device, and it is identified as a prescription device that utilizes accelerometers to measure the motion or acceleration of the skull. These measurements are not to be used for diagnostic purposes.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in Table 1.

TABLE 1—CRANIAL MOTION MEASUREMENT DEVICE RISKS TO HEALTH AND MITIGATION MEASURES

Identified risks	Mitigation measures
Adverse tissue reaction	Biocompatibility evaluation.
Equipment malfunction leading to injury to user or patient	Labeling.
	Electrical safety, thermal, and mechanical testing.
	Electromagnetic compatibility testing.
Inaccurate measurement	Labeling.
	Clinical performance testing.
	Hardware and software verification, validation, and hazard analysis.
	Electromagnetic compatibility testing.
Use error	Labeling.
	Hardware and software verification, validation, and hazard analysis.
	Labeling.

FDA believes that the special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness.

Cranial motion measurement devices are not safe for use except under the

supervision of a practitioner licensed by law to direct the use of the device. As such, the device is a prescription device and must satisfy prescription labeling requirements (see 21 CFR 801.109 (*Prescription devices*)).

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k), if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and

effectiveness of the device. For this type of device, FDA believes premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, is planning to exempt the device from the premarket notification requirements under section 510(m) of the FD&C Act. Once finalized, persons who intend to market this device type need not submit a 510(k) premarket notification containing information on the cranial motion measurement device prior to marketing.

II. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801 regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 882

Medical devices; Neurological devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 882 is amended as follows:

PART 882—NEUROLOGICAL DEVICES

■ 1. The authority citation for part 882 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 882.1630 to subpart B to read as follows:

§ 882.1630 Cranial motion measurement device.

(a) *Identification.* A cranial motion measurement device is a prescription device that utilizes accelerometers to measure the motion or acceleration of the skull. These measurements are not to be used for diagnostic purposes.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The technical parameters of the device, hardware and software, must be fully characterized and include the following information:

(i) Hardware specifications must be provided. Additionally, verification and validation testing as well as a hazard analysis must be performed.

(ii) Software must be described in detail in the Software Requirements Specification (SRS) and Software Design Specification (SDS). Additionally, software verification and validation testing as well as a hazard analysis must be performed.

(2) The device parts that contact the patient must be demonstrated to be biocompatible.

(3) The device must be designed and tested for electrical, thermal, and mechanical safety, and electromagnetic compatibility (EMC).

(4) Clinical performance testing must demonstrate the accuracy, precision, stability, and repeatability of measuring cranial motion per the intended use in the intended use environment.

(5) The labeling must include:

(i) The intended use population and the intended use environment.

(ii) Instructions for technicians to convey to patients regarding the collection of cranial acceleration data to ensure device measurement accuracy, precision, stability, and repeatability.

(iii) Information allowing clinicians to understand potential sources of variability in the measurement to help recognize and identify changes in the measurement.

Dated: July 24, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–15895 Filed 7–27–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 884

[Docket No. FDA–2017–N–1914]

Medical Devices; Obstetrical and Gynecological Devices; Classification of the Closed Loop Hysteroscopic Insufflator With Cutter-Coagulator

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is

classifying the closed loop hysteroscopic insufflator with cutter-coagulator into class II (special controls). The special controls that will apply to the device are identified in this order, and will be part of the codified language for the closed loop hysteroscopic insufflator with cutter-coagulator classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective July 28, 2017. The classification was applicable on March 28, 2014.

FOR FURTHER INFORMATION CONTACT:

Veronica Price, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G116, Silver Spring, MD 20993–0002, 301–796–6538.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, also known as De Novo classification, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification

under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of “low-moderate risk” or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA shall classify the device by written order within 120 days. This classification will be the initial classification of the device.

On September 5, 2013, IOGYN, Inc., submitted a request for classification of the IOGYN System, Models FG–0200, FG–0201, and FG–0202 under section 513(f)(2) of the FD&C Act.

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1). FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on March 28, 2014, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 884.1710.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for a closed loop hysteroscopic insufflator with cutter-coagulator will need to comply with the special controls named in the final order. A De Novo classification decreases regulatory burdens. When FDA classifies a device type as class I or II via the De Novo pathway, other manufacturers do not

have to submit a De Novo request or premarket approval application in order to market the same type of device, unless the device has a new intended use or technological characteristics that raise different questions of safety or effectiveness. Instead, manufacturers can use the less burdensome pathway of 510(k), when necessary, to market their device, and the device that was the subject of the original De Novo classification can serve as a predicate device for additional 510(k)s from other manufacturers.

The device is assigned the generic name closed loop hysteroscopic insufflator with cutter-coagulator, and it is identified as a prescription device configured for hysteroscopic insufflation, resection, and coagulation. It is used to perform diagnostic and surgical procedures (*i.e.*, resection and coagulation). This device type contains a closed loop recirculating fluid management system for the controlled delivery of filtered distension fluid. This device type also contains a bipolar radiofrequency device used in conjunction with a hysteroscope for resection and coagulation of intrauterine tissues.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in Table 1:

TABLE 1—CLOSED LOOP HYSTEROSCOPIC INSUFFLATOR WITH CUTTER-COAGULATOR RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Adverse tissue reaction	Biocompatibility. Labeling.
Equipment malfunction leading to injury	Non-clinical Performance Testing. Software Verification, Validation, and Hazards Analysis. Labeling. Training.
Recirculated fluid causes adverse tissue reaction	Biocompatibility. Non-clinical Performance Testing.
Fluid overload, embolism, perforation or other adverse events	Non-clinical Performance Testing. Software Verification, Validation, and Hazards Analysis. Labeling. Training.
Infection	Sterility. Shelf Life Testing. Non-clinical Performance Testing.
Electromagnetic interference/electrical safety issues	Electromagnetic Compatibility Testing. Electrical Safety Testing. Labeling.
Operator error leading to patient injury	Labeling. Training.

FDA believes that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness.

Closed loop hysteroscopic insufflators with cutter-coagulator are not safe for use except under the supervision of a practitioner licensed by law to direct use of the device. As such, the device is a prescription device and must satisfy

prescription labeling requirements (see 21 CFR 801.109 *Prescription devices*).

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k), if

FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification (510(k)), prior to marketing the device, which contains information on the closed loop hysteroscopic insufflator with cutter-coagulator they intend to market.

II. Analysis of Environmental Impact

We have determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120, and the collections of information in part 801 regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 884

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 884 is amended as follows:

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

- 1. The authority citation for part 884 is revised to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

- 2. Add § 884.1710 to subpart B to read as follows:

§ 884.1710 Closed loop hysteroscopic insufflator with cutter-coagulator.

(a) *Identification.* A closed loop hysteroscopic insufflator with cutter-

coagulator is a prescription device configured for hysteroscopic insufflation, resection, and coagulation. It is used to perform diagnostic and surgical procedures (*i.e.*, resection and coagulation). This device type contains a closed-loop recirculating fluid management system for the controlled delivery of filtered distension fluid. This device type also contains a bipolar radiofrequency device used in conjunction with a hysteroscope for resection and coagulation of intrauterine tissues.

(b) *Classification.* Class II (special controls). The special control(s) for this device are:

(1) The patient-contacting components of the device must be demonstrated to be biocompatible.

(2) Software validation, verification, and hazard analysis must be provided.

(3) Electrical equipment safety, including appropriate thermal and mechanical safety and electromagnetic compatibility (EMC) testing must be performed.

(4) Device components that are labeled sterile must be validated to a sterility assurance level of 10^{-6} .

(5) Shelf-life testing that demonstrates the device packaging maintains sterility and the functionality of the device is maintained following simulated shipping and handling must be provided to support the proposed shelf life.

(6) Non-clinical testing data must demonstrate the performance characteristics of the device. Detailed protocols and the test reports must be provided for each test.

(i) The following tests must be performed for the resection portion of the device:

(A) Mechanical testing to assess critical joint strength.

(B) Device electrode temperature testing.

(C) Coagulation depth testing.

(D) Simulated use testing.

(E) Device durability testing.

(ii) The following tests must be performed for the fluid management portion of the device:

(A) Mechanical testing to assess tensile strength of connections.

(B) Pressure testing that demonstrates the following parameters, including accuracy of the pressure displayed; appropriate detection and response to overpressure conditions; activation of a secondary overpressure relief valve at the maximum safe level; and all accessories within the fluid path meet the pressure requirements.

(C) Fluid delivery volume testing that demonstrates that the maximum fluid volume delivered is below a predefined level.

(D) Flow rate testing.

(E) Simulated use testing.

(F) Filtration testing.

(G) Blood filtration capacity testing.

(H) Tissue collection capacity testing.

(I) Filtrate characterization and testing that demonstrates that the continuous reintroduction of filtrate into the uterus does not pose a safety risk.

(7) Clinician labeling must include:

(i) Specific instructions and the clinical training needed for the safe use of the device.

(ii) Appropriate warnings, precautions, and information related to overpressurization.

(iii) Appropriate EMC information.

(iv) An expiration date/shelf life.

Dated: July 24, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–15892 Filed 7–27–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Parts 3, 20, 64, 67, 80, 82, 83, 84, 104, 105, 109, 110, 115, 117, 120, 133, 135, 136, 137, 138, 151, 155, 157, 159, 161, 162, 164, 165, 174, and 181

46 CFR Parts 4, 28, 31, 39, 44, 50, 58, 63, 69, 71, 107, 110, 111, 116, 120, 127, 153, 154, 161, 162, 170, 177, 182, and 189

[Docket No. USCG–2016–0498]

Navigation and Navigable Waters, and Shipping; Technical, Organizational, and Conforming Amendments

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: This final rule makes non-substantive technical, organizational, and conforming amendments to existing Coast Guard regulations. This rule will have no substantive effect on the regulated public.

DATES: This final rule is effective July 28, 2017.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG–2016–0498, which is available at <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: If you have questions on this final rule, call or email LCDR Felicia Raybon, Coast Guard; telephone 202–372–1499, email Felicia.K.Raybon@uscg.mil.

SUPPLEMENTARY INFORMATION:

Table of Contents for Preamble

- I. Abbreviations
- II. Regulatory History
- III. Basis and Purpose
- IV. Discussion of the Rule
- V. Regulatory Analyses
 - A. Regulatory Planning and Review
 - B. Small Entities
 - C. Assistance for Small Entities
 - D. Collection of Information
 - E. Federalism
 - F. Unfunded Mandates Reform Act
 - G. Taking of Private Property
 - H. Civil Justice Reform
 - I. Protection of Children
 - J. Indian Tribal Governments
 - K. Energy Effects
 - L. Technical Standards
 - M. Environment

I. Abbreviations

CFR Code of Federal Regulations
 COLREGS International Regulations for Preventing Collisions at Sea
 DHS Department of Homeland Security
 FR Federal Register
 MMSI Maritime Mobile Service Identifier
 OMB Office of Management and Budget
 Pub. L. Public Law
 § Section symbol
 USACE U.S. Army Corps of Engineers
 U.S.C. United States Code
 VMRS Vessel Movement Reporting System
 VTS Vessel Traffic Services

II. Regulatory History

We did not publish a notice of proposed rulemaking for this rule. Under Title 5 of the United States Code (U.S.C.), section 553(b)(A), the Coast Guard finds that this rule is exempt from notice and public comment rulemaking requirements because these changes involve rules of agency organization, procedure, or practice. In addition, the Coast Guard finds that notice and comment procedures are unnecessary under 5 U.S.C. 553(b)(B), as this rule consists only of technical and editorial corrections, and these changes will have no substantive effect on the public. Under 5 U.S.C. 553(d)(3), the Coast Guard finds that, for the same reasons, good cause exists for making this final rule effective upon publication in the **Federal Register**.

III. Basis and Purpose

This rule, which becomes effective on July 28, 2017, makes technical and editorial corrections throughout titles 33 and 46. These changes are necessary to correct errors, change addresses, and make other non-substantive changes that improve the clarity of the Code of Federal Regulations (CFR). This rule does not create or change any substantive requirements.

This final rule is issued under the authority of 5 U.S.C. 552(a) and 553, 14 U.S.C. 2(3), 633; 33 U.S.C. 471 and 499;

46 U.S.C. 2103, 3306, 3703, 5104, and 7701; and Department of Homeland Security Delegation No. 0170.1.

IV. Discussion of the Rule

The Coast Guard periodically issues technical, organizational, and conforming amendments to existing regulations in titles 33 and 46 of the CFR. These “technical amendments” provide the public with more accurate and current regulatory information, but do not change the effect on the public of any Coast Guard regulations.

This rule amends the following sections of title 33 in the CFR:

In § 3.04–1, the Coast Guard adds new paragraph (c), which includes information about the location and boundaries of the Activities Europe Marine Inspection Zone in relation to the Coast Guard “Atlantic Area” to reflect a recent organizational change that placed Activities Europe under the operational and administrative control of the Coast Guard’s Atlantic Area Command. The change does not involve a boundary move and only clarifies § 3.04–1 to describe the location of the eastern boundary, and the supervising commander. That eastern boundary is already established in the Activities Far East regulation at 33 CFR 3.70–20; this change states the same boundary from the perspective of Activities Europe. Activities Europe has reported to Coast Guard Atlantic Area (LANTAREA) since 2006 (see 71 FR 35816).

Section 20.302(b) and (c) are revised to include the toll free telephone and fax numbers for the U.S. Coast Guard Administrative Law Judge Docketing Center.

The tables of § 20.304(d) and (g) are revised to accommodate different methods of mail delivery to include Priority or Express Mail with signature confirmation as an alternative to Certified Mail, return receipt.

In § 64.03(b)(1), the text “Subchapter D” is replaced with the text “Subchapter E” to correct a longstanding error in the cross-reference. Subchapter D, “International Navigation Rules,” does not address dredging pipelines, which are the subject of § 64.03(b)(1). Annex V to subchapter E, “Inland Navigation Rules,” addresses lights on dredging pipelines. Regulations for these lights have never been in subchapter D.

This rule revises § 67.10–25(a) to remove a redundant address.

This rule corrects a typographical error in one of the geographical coordinates in § 80.155(b).

Also, this rule corrects a typographical error in § 80.502(a) by

removing the letter “s” from “Little Egg Inlet.”

In § 82.5, this rule changes the text “33 CFR 88.30(h)” to “33 CFR 83.30(h),” to conform to the regulatory redesignation made by a 2014 final rule (see 79 FR 37898, July 2, 2014).

This rule revises §§ 83.09(e)(i) and 83.24(d) by adding minor rewordings and terminology revisions to conform to the International Regulations for Preventing Collisions at Sea (COLREGS).

This rule redesignates existing § 83.24(i), as new paragraph (j), and existing paragraph (j) as new paragraph (i). The new paragraph (i), removes the text “paragraph (a), (c), or (i)” and adds, in its place, the text “paragraphs (a), (c), or (j).” These changes are made to conform to COLREGS.

This rule amends § 84.15 by redesignating paragraph (b) as (b)(i) and redesignating paragraph (c) as (b)(ii), and redesignating the note to paragraph (c) as the note to paragraph (b)(ii) to align CFR numbering to conform to COLREGS.

This rule updates the Coast Guard’s address information in §§ 104.400(b), 120.305(a), 133.3(b), 133.25(c), 135.9, 136.3, 136.5(b), 136.101(b), 137.15, 138.45(a), 151.1510(a)(3)(ii), 151.2025(b), 151.2026(b), 157.100(b), 157.200(b), 159.4(a), 159.12(c), 159.15(a) and (c), 159.17(a), and 159.19(a). Also, in § 138.45(a), the Coast Guard updates the phone number and fax number for the Coast Guard’s National Pollution Funds Center.

In § 105.110(b), this rule revises the internal cross-references to conform to regulatory changes made by a 2007 rule (72 FR 3492, Jan. 25, 2007), which does not affect the meaning of the cross-references.

This rule amends the authority citation in part 109. This change makes necessary conforming amendments to reflect the transfers of functions from the Secretary of War to the Secretary of Transportation to the Secretary of Homeland Security, and to eliminate superfluous references in law.

This rule revises § 110.79c to correct erroneous coordinates describing the boundaries of the anchorage at Fish Creek Harbor, WI and to add a note that the Town of Gibraltar, WI regulates the use of vessels and moorings in that area. This technical amendment does not alter the existing boundaries of the anchorage.

This rule redesignates §§ 115.10 through 115.30. Those redesignations are as follows: Current § 115.10, “Limiting date in permits,” becomes § 115.15; current § 115.15, “Permit bonds,” becomes § 115.20; current

§ 115.20, “Transfer of permits,” becomes § 115.30; and current § 115.30, “Sufficiency of State authority for bridges” becomes § 115.10. The purpose of these redesignations is to have the state authority regulations appear together in the CFR.

This rule amends §§ 115.05 and 115.50(e) introductory text and (e)(1) by replacing the word “extract” with “excerpt.” The purpose of this change is to use a term more clearly understood to mean that the applicant of a bridge permit should “select” a section, instead of “pulling out” a section from the charter, statement of ownership, minutes of the organization, or proceedings when applying for a bridge permit. In addition, this rule corrects grammatical errors in § 115.50(e) by adding the word “an” before “excerpt” and adding the word “the” before “minutes.”

This rule amends language in § 115.50 “Application for bridge permits” paragraph (h)(2) by changing the opening phrase as follows: (1) “Currents” is being changed to “current” because inland rivers have one current, which only flows one way; (2) “tidal water” is being added to clarify that the current flows two ways (ebbs and flows); (3) “strength of current” is being removed because it is a function of the navigation study, which comes prior to the bridge application process; and (4) “low and high water” is removed because of redundancy in paragraph (h)(3).

This rule clarifies a phrase in § 115.50(h)(3) by replacing the text “the plane above which flood waters have not remained more than 2 percent of the time” with the text “the 2 percent flowline (the plane above which flood waters have not remained more than 2 percent of the time)” to better describe the records of river heights to be shown if they are available.

This rule amends § 117.55(a) by replacing “through” with “and” because there are only two other sections within the range described: another section was removed by a 2006 rule (71 FR 70305, Dec. 4, 2006).

This rule amends § 155.480(b)(2)(iii) by changing the internal cross-reference to conform to regulatory redesignations made by a 2013 rule (78 FR 42642, July 16, 2013), which does not affect the meaning of the cross-references. A 2015 technical amendment attempted to correct the cross-reference but inadvertently omitted the citations to paragraphs (b)(2) and (3).

This rule amends §§ 155.1065(a), 155.1070(f), 155.5035(k), 155.5061(a), (c), and (f), 155.5065(a), 155.5067(a), and section 6.5 of appendix B to part

155 to change the name of the office listed in these regulations to reflect delegation from Commandant (CG-CVC) to Commandant (CG-MER).

This rule amends §§ 155.1065(h), 155.1070(g), and 155.5075(a) and (b) to change the name of the office listed in these regulations to reflect delegation from Director of Inspections and Compliance (CG-5PC) to Director of Incident Management and Preparedness Policy (CG-5RI).

Sections 155.4025 and 155.4055(d) and (f) are revised to show a change in the office name from “Director of Prevention Policy (CG-5P)” to “Assistant Commandant for Response Policy (CG-5R)” to reflect that office’s delegation.

This rule amends the formatting and specific portions of the text in the Table to § 161.12(c) for clarity and ease of reading. The changes include:

(a) Formatting changes to disaggregate one column into two columns and add letters and numbers to each row;

(b) Moving the Maritime Mobile Service Identifier (MMSI) from the “VTS and VMRS Centers” column to the “Center call sign and MMSI” column; and

(c) Removing the name of the “Center MMSI call sign” column, and adding in its place, “Center call sign and MMSI.”

This rule also amends the table heading and text in Table to § 161.12(c) for the following reasons:

(a) Revise the frequency listed for Buzzards Bay Control from “156.600 MHz (Ch. 12)” to “156.550 MHz (Ch. 11)” to reflect the new listening frequency, as approved by the Federal Communications Commission;

(b) Correct a longitude coordinate for Buzzards Bay Control to accurately reflect the correct position of the Buzzards Bay Entrance Light;

(c) Revise the coordinate location for Puget Sound Seattle Traffic (Ch. 5A) to reflect the closure of the Canadian traffic management area “Tofino Traffic.” As a result of this closure, we are changing the description of the sub-areas for our joint U.S./Canadian Vessel Traffic Services (VTS) area. Neither the size of the area has changed nor has the radio frequency. The change only reflects the way the Coast Guard describes and identifies the sub-areas;

(d) Revise the name of the traffic management area Puget Sound from “Tofino Traffic 003160012” to “Prince Rupert Traffic 003160013,” and to update the coordinates for the monitoring area to reflect the closure of Tofino Traffic; and

(e) Revise the coordinate location for Puget Sound Victoria Traffic to reflect

the closure of the Canadian traffic management area “Tofino Traffic.”

This rule amends the Table to § 161.45(b) by revising the heading and by removing an “*” to correct a typographical error.

This rule amends § 161.50 by adding symbols to the coordinates for Vessel Traffic Service San Francisco to denote degrees.

This rule amends the introduction to § 161.55 by removing the text referring to the waters known as “the Strait of Juan de Fuca, Haro Strait, Boundary Pass, and the Strait of Georgia to the Washington State coastline” and the areas covering those navigable waters including “Puget Sound, Hood Canal, Possession Sound, the San Juan Island Archipelago, Rosario Strait, Guemes Channel, Bellingham Bay, the U.S. waters of the Strait of Juan de Fuca and the Strait of Georgia,” and adding, in its place, reference to the “U.S. navigable waters of the Salish Sea.” In 2009, the U.S. Board on Geographic Names made a determination that waters previously described in the VTS Puget Sound should now be recognized as the “U.S. navigable waters of Salish Sea,” which replaces the removed text. The deleted text is no longer necessary to describe the VTS Puget Sound area. Also, we are converting some of the latitude and longitude coordinates so that they are in a more common positioning format of degrees, minutes, and decimal minutes instead of degrees, minutes, and seconds.

This rule amends § 161.55(a) by removing the text referring to all the waters including “Strait of Juan de Fuca and its offshore approaches, southern Georgia Strait, the Gulf and San Juan Archipelagos, Rosario Strait, Boundary Pass and Haro Strait, and Strait of Georgia,” and adding in its place, reference to “all navigable waters of the Salish Sea.” In 2009, the U.S. Board on Geographic Names made a determination that waters previously described in the VTS Puget Sound should now be recognized as the “U.S. navigable waters of Salish Sea,” which replaces the removed text for the same reasons, discussed in the preceding paragraph. In paragraph (a), this rule also removes reference to “Tofino” and adds a reference to “Prince Rupert” to reflect the closure of Tofino Traffic.

This rule amends § 162.205(a)(3)(i) and (b)(2)(i) by updating the cross-reference from “part 80” to “part 83” to correctly reference the inland navigation rules in 33 CFR part 83 instead of the international navigation rules in 33 CFR part 80.

This rule amends §§ 164.33(a)(3)(ii) and 164.72(b)(2)(i)(C) by removing

references to the U.S. Army Corps of Engineers (USACE) from this section, as the USACE no longer issues river current publications.

This rule amends the note to paragraph (b) of § 164.46 by adding examples of the types of fishing industry vessels, consistent with 46 U.S.C. 2101. The 2015 rule covering Automatic Identification System requirements (80 FR 5282, Jan. 30, 2015) amended § 164.46(b)(2) to include fishing industry vessels, and described them as “any vessel engaged in the fishing trade.”

This rule amends § 165.100(d)(5) by removing typographical errors from the coordinates listed in this section and changing the coordinates to accurately reflect the correct position for Buzzards Bay Entrance Light.

This rule removes § 165.T0704 and adds § 165.704 in its place. This change reflects that this is a permanent regulation and not a temporary regulation. Also, in paragraph (c)(3), the telephone number is updated.

This rule removes § 165.766 from the CFR as it is duplicative and unnecessary. Section 165.766 became effective after a 2007 interim rule (72 FR 43535, August 6, 2007) was published. However, a 2008 final rule (73 FR 27746, May 14, 2008) made a slight boundary change from the 2007 interim rule, and finalized the interim rule, under a new section number, § 165.770.

This rule revises the heading of § 174.123 by removing “numbered” from the title. Also, we remove the title, “Report of Certificates of Number Issued to Boats, to the Coast Guard” from Coast Guard Form CGHQ-3923 because the title does not reflect the contents of the form. The Coast Guard plans to seek approval from the Office of Management and Budget (OMB) to create a new version of the form with a different title.

This rule revises § 181.3 by removing the term and definition of “Model year” because it is superseded by the model year set in the Coast Guard Authorization Act of 2015 (see Pub. L. 114-120, 130 Stat. 27, February 8, 2016).

This rule makes changes in the following sections of title 46 in the CFR:

This rule amends § 4.07-10(a)(4) by removing reference to Coast Guard Form CG-2636, as this form has been cancelled. There is no impact on the public because this form was used internally by Coast Guard investigative officers.

This rule replaces the name of the organization accepted by the Commandant to receive and process casualty data in § 28.80(d)(1) from “Marine Index Bureau” to “Verisk

Insurance Solutions.” Verisk Insurance Solutions is the same company as Marine Index Bureau; however, the company name was changed. This rule also removes “Floor 22-8” from the address listed in § 28.80(d)(1) because the current address for Verisk Insurance Solutions does not contain this information.

This rule updates the Coast Guard’s address information in §§ 28.1105(a), 31.10-5(a), 39.1003, 44.320(a), 50.10-23, 63.10-1, 63.25-9(a), 69.15(a), 71.65-15(a)(2), 107.317(b), 110.25-3(a)(1), 116.202(a), 127.120(b), 153.9(b), 154.22(a), 161.010-1(a), 161.010-4(a), 162.017-6(a), 162.018-8(a), 162.050-7(a), 162.060-10(a) and (b)(1), 162.060-14(b), 162.060-42(a)(3) and (g), 170.010, 170.100(b), 177.202(d), 177.410(b)(5), and 189.55-15(a)(2).

This rule amends § 39.2007(e) and (f) by correcting an inaccurate cross-reference inadvertently made in the 2013 rule (78 FR 42596, July 16, 2013). The existing cross-reference is to § 39.2009(c) and (d), which do not exist. This rule amends tables to §§ 58.50-5(a), 58.50-10(a), and 182.440(a)(1) by shifting particular rows in each table to correct a misprint. In each existing table the contents of the final row are incorrectly shifted to the left such that the contents do not line up with the headings. This rule also reformats the table titles.

This rule amends the authority citation for part 110 by removing “33 U.S.C. 1509” because Deepwater Ports’ regulations in 33 CFR subchapter NN no longer refer to 46 CFR subchapter J “Electrical Engineering” regulations.

This rule amends § 110.15-1 by removing the definitions of “Marine inspector or inspector” and “Qualified person” as these terms are not used in 46 CFR subchapter J. This rule amends § 111.33-1 by removing an outdated reference to § 111.30-21, which was removed from the CFR in 1996 (61 FR 4132, Feb. 2, 1996).

This rule amends §§ 111.105-19 and 120.340(p) by correcting a typographical error in the cross-referenced citations. The existing cross-reference in § 111.105-19 is to § 111.105-19 itself, but should be to § 111.105-9 on explosion-proof and flameproof equipment. The existing cross-reference in § 120.340(p) is to Table 120.3340(p), but should be to Table 1 to § 120.340(p).

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on these statutes or Executive orders.

A. Regulatory Planning and Review

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review) 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 (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs) directs agencies to reduce regulation and control regulatory costs and provides that “for every one new regulation issued, at least two prior regulations be identified for elimination, and that the cost of planned regulations be prudently managed and controlled through a budgeting process.”

The Office of Management and Budget (OMB) has not designated this rule a significant regulatory action under section 3(f) of Executive Order 12866. Accordingly, OMB has not reviewed it. Because this rule is not a significant regulatory action, this rule is exempt from the requirements of Executive Order 13771. See the OMB 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). A regulatory analysis (RA) follows.

Because this rule involves non-substantive changes and internal agency practices and procedures, it will not impose any additional costs on the public. The benefit of the non-substantive changes is increased clarity of regulations.

B. Small Entities

Under the Regulatory Flexibility Act, 5 U.S.C. 601-612, rules exempt from the notice and comment requirements of the Administrative Procedure Act are not required to examine the impact of the rule on small entities. Nevertheless, we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

There is no cost to this final rule, and we do not expect it will have an impact on small entities because the provisions of this rule are technical and non-substantive. It will have no substantive effect on the public and will impose no additional costs. Therefore, the Coast Guard certifies under 5 U.S.C. 605(b) that this final rule will not have a significant economic impact on a substantial number of small entities.

C. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please consult LCDR Nicole Burgess by phone at 202–372–1493 or via email at Nicole.S.Burgess@uscg.mil. 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.

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).

D. Collection of Information

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

E. Federalism

A rule has implications for federalism under Executive Order 13132 (“Federalism”) if it has a substantial direct effect on 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.

F. 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 1 year. Though this final rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

G. Taking of Private Property

This final rule will not cause a taking of private property or otherwise have taking implications under Executive Order 12630 (“Governmental Actions and Interference with Constitutionally Protected Property Rights”).

H. Civil Justice Reform

This final rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988 (“Civil Justice Reform”), to minimize litigation, eliminate ambiguity, and reduce burden.

I. Protection of Children

We have analyzed this final rule under Executive Order 13045 (“Protection of Children from Environmental Health Risks and Safety Risks”). This final rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

J. Indian Tribal Governments

This final 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.

K. Energy Effects

We have analyzed this final rule under Executive Order 13211 (“Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use”). We have determined that it is not a “significant energy action” under that order because it is not a “significant regulatory action” under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of OMB's Office of Information and Regulatory

Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

L. Technical Standards

The National Technology Transfer and Advancement Act (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the OMB, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

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

M. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have concluded 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 is categorically excluded under section 2.B.2 and figure 2–1, paragraphs (34)(a) and (34)(b) of the Instruction. This final rule involves amendments to regulations that are editorial or procedural. A Record of Environmental Consideration (REC) supporting this determination is available in the docket where indicated under **ADDRESSES**.

List of Subjects

33 CFR Part 3

Organization and functions (Government agencies).

33 CFR Part 20

Administrative practice and procedure, Hazardous substances, Oil pollution, Penalties, Water pollution control.

33 CFR Part 64

Navigation (water), Reporting and recordkeeping requirements.

33 CFR Part 67

Continental shelf, Navigation (water), Reporting and recordkeeping requirements.

33 CFR Part 80

Navigation (water), Treaties, Waterways.

33 CFR Part 82

Navigation (water), Treaties.

33 CFR Part 83

Fishing vessels, Navigation (water), Waterways.

33 CFR Part 84

Navigation (water), Waterways.

33 CFR Part 104

Maritime security, Reporting and recordkeeping requirements, Security measures, Vessels.

33 CFR Part 105

Maritime security, Reporting and recordkeeping requirements, Security measures.

33 CFR Parts 109 and 110

Anchorage grounds.

33 CFR Part 115

Administrative practice and procedure, Bridges, Reporting and recordkeeping requirements.

33 CFR Part 117

Bridges.

33 CFR Part 120

Passenger vessels, Reporting and recordkeeping requirements, Security measures, Terrorism.

33 CFR Part 133

Intergovernmental relations, Oil pollution, Reporting and recordkeeping requirements.

33 CFR Part 135

Administrative practice and procedure, Continental shelf, Insurance, Oil pollution, Reporting and recordkeeping requirements.

33 CFR Part 136

Administrative practice and procedure, Advertising, Claims, Oil pollution, Penalties, Reporting and recordkeeping requirements.

33 CFR Part 137

Administrative practice and procedure, Environmental protection, Intergovernmental relations, Oil pollution, Reporting and recordkeeping requirements.

33 CFR Part 138

Hazardous materials transportation, Insurance, Oil pollution, Reporting and recordkeeping requirements, Surety bonds, Vessels, Water pollution control.

33 CFR Part 151

Administrative practice and procedure, Oil pollution, Penalties, Reporting and recordkeeping requirements, Water pollution control.

33 CFR Part 155

Alaska, Hazardous substances, Oil pollution, Reporting and recordkeeping requirements.

33 CFR Part 157

Cargo vessels, Oil pollution, Reporting and recordkeeping requirements.

33 CFR Part 159

Alaska, Incorporation by reference, Reporting and recordkeeping requirements, Sewage disposal, Vessels.

33 CFR Part 161

Harbors, Navigation (water), Reporting and recordkeeping requirements, Vessels, Waterways.

33 CFR Part 162

Navigation (water), Waterways.

33 CFR Part 164

Marine, Navigation (water), Reporting and recordkeeping requirements, Waterways.

33 CFR Part 165

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

33 CFR Part 174

Intergovernmental relations, Marine safety, Reporting and recordkeeping requirements.

33 CFR Part 181

Labeling, Marine safety, Reporting and recordkeeping requirements.

46 CFR Part 4

Administrative practice and procedure, Drug testing, Investigations, Marine safety, National Transportation Safety Board, Nuclear vessels, Radiation protection, Reporting and recordkeeping requirements, Safety, Transportation.

46 CFR Part 28

Alaska, Fire prevention, Fishing vessels, Marine safety, Occupational safety and health, Reporting and recordkeeping requirements, Seamen.

46 CFR Part 31

Cargo vessels, Marine safety, Reporting and recordkeeping requirements.

46 CFR Part 39

Cargo vessels, Fire prevention, Hazardous materials transportation, Incorporation by reference, Marine safety, Occupational safety and health, Reporting and recordkeeping requirements.

46 CFR Parts 44, 50, 58, and 110

Reporting and recordkeeping requirements, Vessels.

46 CFR Parts 63 and 111

Vessels.

46 CFR Part 69

Penalties, Reporting and recordkeeping requirements, Vessels.

46 CFR Part 71

Marine safety, Passenger vessels, Reporting and recordkeeping requirements.

46 CFR Part 107

Marine safety, Oil and gas exploration, Reporting and recordkeeping requirements, Vessels.

46 CFR Part 116

Fire prevention, Marine safety, Passenger vessels, Seamen.

46 CFR Part 120

Marine safety, Passenger vessels.

46 CFR Part 127

Cargo vessels, Fire prevention, Marine safety, Occupational safety and health, Reporting and recordkeeping requirements, Seamen.

46 CFR Part 153

Administrative practice and procedure, Cargo vessels, Hazardous materials transportation, Marine safety, Reporting and recordkeeping requirements, Water pollution control.

46 CFR Part 154

Cargo vessels, Gases, Hazardous materials transportation, Marine safety, Reporting and recordkeeping requirements.

46 CFR Part 161

Fire prevention, Incorporation by reference, Marine safety, Reporting and recordkeeping requirements.

46 CFR Part 162

Fire prevention, Marine safety, Oil pollution, Reporting and recordkeeping requirements.

46 CFR Part 170

Marine safety, Reporting and recordkeeping requirements, Vessels.

46 CFR Part 177

Marine safety, Passenger vessels, Reporting and recordkeeping requirements.

46 CFR Part 182

Marine safety, Passenger vessels.

46 CFR Part 189

Marine safety, Oceanographic research vessels, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR parts 3, 20, 64, 67, 80, 82, 83, 84, 104, 105, 109, 110, 115, 117, 120, 133, 135, 136, 137, 138, 151, 155, 157, 159, 161, 162, 164, 165, 174, and 181 and 46 CFR parts 4, 28, 31, 39, 44, 50, 58, 63, 69, 71, 107, 110, 111, 116, 120, 127, 153, 154, 161, 162, 170, 177, 182, and 189 as follows:

Title 33—Navigation and Navigable Waters

PART 3—COAST GUARD AREAS, DISTRICTS, SECTORS, MARINE INSPECTION ZONES, AND CAPTAIN OF THE PORT ZONES

■ 1. The authority citation for part 3 continues to read as follows:

Authority: 14 U.S.C. 92 & 93; Pub. L. 107–296, 116 Stat. 2135; Department of Homeland Security Delegation No. 0170.1, para. 2(23).

■ 2. In § 3.04–1, add paragraph (c) to read as follows:

§ 3.04–1 Atlantic Area.

* * * * *

(c)(1) Activities Europe is a part of Atlantic Area. Activities Europe's office is located in Schinnen, the Netherlands. The boundaries of Activities Europe's Marine Inspection Zone coincide with the boundaries of the Atlantic Area, which are described in paragraph (b) of this section, excluding the First, Fifth, Seventh, Eighth, and Ninth Coast Guard Districts.

(2) Only for this part, the boundary between Activities Europe and Activities Far East Marine Inspection Zones is demarked by a southerly line bisecting the border of the Republic of India and the Islamic Republic of Pakistan.

PART 20—RULES OF PRACTICE, PROCEDURE, AND EVIDENCE FOR FORMAL ADMINISTRATIVE PROCEEDINGS OF THE COAST GUARD

■ 3. The authority citation for part 20 continues to read as follows:

Authority: 33 U.S.C. 1321; 42 U.S.C. 9609; 46 U.S.C. 7701, 7702; Department of

Homeland Security Delegation No. 0170.1, para. 2(73).

■ 4. Revise paragraphs (b) and (c) of § 20.302 to read as follows:

§ 20.302 Filing of documents and other materials.

* * * * *

(b) The telephone number is: 410–962–5100. The toll-free telephone number is: 1–866–612–7524.

(c) The fax number is: 410–962–1746. The toll-free fax number is: 1–877–243–3453.

* * * * *

■ 5. Amend § 20.304 as follows:

■ a. Revise the heading and entries 1 and 2 of Table 20.304(d);

■ b. In Table 20.304(e), remove the text “Table 20.304(e)” and add, in its place, the text “Table 1 to § 20.304(e)”;

■ c. In Table 20.304(f), remove the text “Table 20.304(f)” and add, in its place, the text “Table 1 to § 20.304(f)”;

■ d. Revise the heading and entry 3 of Table 20.304(g).

The revisions read as follows:

§ 20.304 Service of documents.

* * * * *

(d) * * *

TABLE 1 TO § 20.304(d)—HOW TO SERVE FILED DOCUMENTS

Type of filed document	Acceptable methods of service
(1) Complaint	(i) Certified mail, return receipt requested; Priority mail with signature confirmation; or Express Mail with signature confirmation. (ii) Personal delivery. (iii) Express-courier service that has receipt capability.
(2) Default motion	(i) Certified mail, return receipt requested; Priority mail with signature confirmation; or Express Mail with signature confirmation. (ii) Personal delivery. (iii) Express-courier service that has receipt capability.
* * * * *	* * * * *

* * * * *

(g) * * *

TABLE 1 TO § 20.304(g)—WHEN SERVICE IS COMPLETE

If method of service used is—	Then service is complete when the document is—
* * * * *	* * * * *
(3) Certified Mail, Priority Mail, Express Mail, or express-courier (Complaint or Default Motion).	(i) Delivered to the person's residence and signed for by a person of suitable age and discretion residing at the individual's residence. (ii) Delivered to the person's office during business hours and signed for by a person of suitable age and discretion.
* * * * *	* * * * *

* * * * *

PART 64—MARKING OF STRUCTURES, SUNKEN VESSELS, AND OTHER OBSTRUCTIONS

- 6. The authority citation for part 64 continues to read as follows:

Authority: 14 U.S.C. 633; 33 U.S.C. 409, 1231; 42 U.S.C. 9118; 43 U.S.C. 1333; Department of Homeland Security Delegation No. 0170.1.

§ 64.03 [Amended]

- 7. Amend § 64.03 as follows:
- a. In paragraph (b)(1), remove the text “Subchapter D” and add, in its place, the text “subchapter E”; and
- b. In paragraph (b)(2), remove the word “Subchapter” and add, in its place, the word “subchapter”.

PART 67—AIDS TO NAVIGATION ON ARTIFICIAL ISLANDS AND FIXED STRUCTURES

- 8. The authority citation for part 67 continues to read as follows:

Authority: 14 U.S.C. 85, 633; 43 U.S.C. 1333; Department of Homeland Security Delegation No. 0170.1.

- 9. Revise § 67.10–25(a) introductory text to read as follows:

§ 67.10–25 Application for tests.

* * * * *

(a) Direct a written request to the Aids to Navigation Division (CG–NAV–1), U.S. Coast Guard Stop 7418, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7418 including:

* * * * *

PART 80—COLREGS DEMARCATION LINES

- 10. The authority citation for part 80 continues to read as follows:

Authority: 14 U.S.C. 2; 14 U.S.C. 633; 33 U.S.C. 151(a).

§ 80.155 [Amended]

- 11. In § 80.155(b), remove the text “41°12′2.900″ N.” and add, in its place, the text “41°12′22.900″ N.”.

§ 80.502 [Amended]

- 12. In § 80.502(a), remove the text “Little Egg Inlets” and add, in its place, the text “Little Egg Inlet”.

PART 82—72 COLREGS: INTERPRETATIVE RULES

- 13. The authority citation for part 82 continues to read as follows:

Authority: 14 U.S.C. 2, 633; 33 U.S.C. 1602; E.O. 11964, 42 FR 4327, 3 CFR, 1977 Comp., p. 88; 49 CFR 1.46(n).

§ 82.5 [Amended]

- 14. In § 82.5, remove the text “33 CFR 88.30(h)” and add, in its place, the text “33 CFR 83.30(h)”.

PART 83—RULES

- 15. The authority citation for part 83 continues to read as follows:

Authority: Sec. 303, Pub. L. 108–293, 118 Stat. 1042 (33 U.S.C. 2071); Department of Homeland Security Delegation No. 0170.1.

§ 83.09 [Amended]

- 16. In § 83.09(e)(i), remove the word “danger”.

§ 83.24 [Amended]

- 17. Amend § 83.24 as follows:
- a. In § 83.24(d), remove the word “apply” and add, in its place, the word “applies”;
- b. Redesignate paragraphs (i) and (j) as paragraphs (j) and (i), respectively; and
- c. In newly redesignated paragraph (i), remove the text “paragraph (a), (c), or (i)” and add, in its place, the text “paragraph (a), (c), or (j)”.

PART 84—ANNEX I: POSITIONING AND TECHNICAL DETAILS OF LIGHTS AND SHAPES

- 18. The authority citation for part 84 continues to read as follows:

Authority: Sec. 303, Pub. L. 108–293, 118 Stat. 1042 (33 U.S.C. 2071); Department of Homeland Security Delegation No. 0170.1.

§ 84.15 [Amended]

- 19. Amend § 84.15 as follows:
- a. Redesignate paragraphs (b) and (c) as paragraphs (b)(i) and (ii);
- b. In newly redesignated paragraph (b)(ii), remove the text “paragraph (b)” and add, in its place, the text “paragraph (b)(i)”; and
- c. Redesignate the Note to paragraph (c) as Note 1 to paragraph (b)(ii).

PART 104—MARITIME SECURITY: VESSELS

- 20. The authority citation for part 104 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–11, 6.14, 6.16, and 6.19; Department of Homeland Security Delegation No. 0170.1.

§ 104.400 [Amended]

- 21. In § 104.400(b), remove the text “Attn: Marine Safety Center, U.S. Coast Guard Stop 7410, 4200 Wilson Boulevard, Suite 400, Arlington, VA 20598–7410”, and add, in its place, the text “Attn: Marine Safety Center, U.S. Coast Guard Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7430”.

PART 105—MARITIME SECURITY: FACILITIES

- 22. The authority citation for part 105 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. 70103; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–11, 6.14, 6.16, and 6.19; Department of Homeland Security Delegation No. 0170.1.

§ 105.110 [Amended]

- 23. In § 105.110(b), remove the text “§ 105.255(c), (e)(1), (e)(3), (f)(1), and (g)(1) and § 105.285(a)(1)” and add, in its place, the text “§ 105.255(c), (f)(2) and (4), (g)(1), and (h)(1) and 105.285(a)(1)”.

PART 109—GENERAL

- 24. Revise the authority citation for part 109 to read as follows:

Authority: 33 U.S.C. 471 and 1231; Pub. L. 107–296, 116 Stat. 2135; Department of Homeland Security Delegation No. 0170.1.

PART 110—ANCHORAGE REGULATIONS

- 25. The authority citation for part 110 continues to read as follows:

Authority: 33 U.S.C. 471, 1221 through 1236, 2071; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1.

- 26. Revise § 110.79c to read as follows:

§ 110.79c Fish Creek Harbor, Fish Creek, Wisconsin.

The area within the following boundaries: Beginning at latitude 45°07′52″ N., longitude 87°14′42″ W.; thence to latitude 45°07′53″ N., longitude 87°14′37″ W.; thence to latitude 45°07′47″ N., longitude 87°14′30″ W.; thence to latitude 45°07′42″ N., longitude 87°14′37″ W.; thence to latitude 45°07′44″ N., longitude 87°14′40″ W.; thence to latitude 45°07′48″ N., longitude 87°14′38″ W.; thence to the point of beginning.

Note 1 to § 110.79c: An ordinance of the Town of Gibraltar, WI, requires moorings to be approved by the Harbor Commission of the Town of Gibraltar and provides for other regulation of the use of vessels and moorings in this area.

PART 115—BRIDGE LOCATIONS AND CLEARANCES; ADMINISTRATIVE PROCEDURES

- 27. The authority citation for part 115 continues to read as follows:

Authority: c. 425, sec. 9, 30 Stat. 1151 (33 U.S.C. 401); c. 1130, sec. 1, 34 Stat. 84 (33 U.S.C. 491); sec. 5, 28 Stat. 362, as amended (33 U.S.C. 499); sec. 11, 54 Stat. 501, as amended (33 U.S.C. 521); c. 753, Title V, sec.

502, 60 Stat. 847, as amended (33 U.S.C. 525); 86 Stat. 732 (33 U.S.C. 535); 14 U.S.C. 633.

§ 115.05 [Amended]

■ 28. In § 115.05 remove the word “extract” and add, in its place, the word “excerpt”.

§§ 115.10, 115.15, 115.20, and 115.30 [Redesignated as §§ 115.15, 115.20, 115.30, and 115.10]

■ 29. Redesignate §§ 115.10, 115.15, 115.20, and 115.30 as §§ 115.15, 115.20, 115.30, and 115.10, respectively.

■ 30. Amend § 115.50 as follows:

■ a. In paragraph (e) introductory text, remove the text “extract from” and add, in its place, the text “an excerpt from the”;

■ b. In paragraph (e)(1), remove the word “extracts” and add, in its place, the word “excerpts”;

■ c. Revise paragraph (h)(2); and

■ d. In paragraph (h)(3), remove the text “available, the plane above which flood waters have not remained more than 2 percent of the time will” and add, in its place, the text “available, the 2 percent flowline (the plane above which flood waters have not remained more than 2 percent of the time) will”.

The revision reads as follows:

§ 115.50 Application for bridge permits.

* * * * *

(h) * * *

(2) The direction of the current or, for tidal waters, the direction of the ebb and flow, will be indicated by arrow(s), and will be shown close to the proposed location of the bridge, and at both ends of the waterway shown on the map of location.

* * * * *

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 31. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; and Department of Homeland Security Delegation No. 0170.1.

§ 117.55 [Amended]

■ 32. Amend § 117.55(a) by removing the text “Subpart A or §§ 117.51 through 117.59 of this part” and adding, in its place, the text “subpart A of this part or §§ 117.51 and 117.59”.

PART 120—SECURITY OF PASSENGER VESSELS

■ 33. The authority citation for part 120 continues to read as follows:

Authority: 33 U.S.C. 1231; Department of Homeland Security Delegation No. 0170.

■ 34. Revise § 120.305(a) to read as follows:

§ 120.305 What is the procedure for examination?

(a) You must submit two copies of each Vessel Security Plan required by § 120.300, or of any Terminal Security Plan or annex required or permitted under § 120.303 or § 128.305 of this chapter, to the Commanding Officer, Marine Safety Center, U.S. Coast Guard, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593 for visitors. Send all mail to: Commanding Officer (MSC), Attn: Marine Safety Center, U.S. Coast Guard Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7430, for examination at least 60 days before embarking passengers on a voyage described in § 120.100.

* * * * *

PART 133—OIL SPILL LIABILITY TRUST FUND; STATE ACCESS

■ 35. The authority citation for part 133 continues to read as follows:

Authority: 33 U.S.C. 2712(a)(1)(B), 2712(d) and 2712(e); Sec. 1512 of the Homeland Security Act of 2002, Pub. L. 107–296, Title XV, Nov. 25, 2002, 116 Stat. 2310 (6 U.S.C. 552(d)); E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351, as amended by E.O. 13286, 68 FR 10619, 3 CFR, 2004 Comp., p. 166; Department of Homeland Security Delegation No. 0170.1., para. 2(80).

§ 133.3 [Amended]

■ 36. In § 133.3(b), remove the text “NPFC MS 7100, U.S. Coast Guard, 4200 Wilson Blvd., Suite 1000, Arlington, VA 20598–7100” and add, in its place, the text “U.S. Coast Guard Stop 7605, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7605”.

§ 133.25 [Amended]

■ 37. In § 133.25(c), remove the text “NPFC CM, MS 7100, U.S. Coast Guard, 4200 Wilson Blvd., Suite 1000, Arlington, VA 20598–7100” and add, in its place, the text “U.S. Coast Guard Stop 7605, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7605”.

PART 135—OFFSHORE OIL POLLUTION COMPENSATION FUND

■ 38. The authority citation for part 135 continues to read as follows:

Authority: 33 U.S.C. 2701–2719; E.O. 12777, 56 FR 54757; Department of Homeland Security Delegation No. 0170.1, para. 2(80).

§ 135.9 [Amended]

■ 39. In § 135.9, remove the text “NPFC MS 7100, U.S. Coast Guard, 4200 Wilson Blvd., Suite 1000, Arlington, VA 20598–7100” and add, in its place, the text “U.S. Coast Guard Stop 7605, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7605”.

PART 136—OIL SPILL LIABILITY TRUST FUND; CLAIMS PROCEDURES; DESIGNATION OF SOURCE; AND ADVERTISEMENT

■ 40. The authority citation for part 136 continues to read as follows:

Authority: 33 U.S.C. 2713(e) and 2714; Sec. 1512 of the Homeland Security Act of 2002, Pub. L. 107–296, Title XV, Nov. 25, 2002, 116 Stat. 2310 (6 U.S.C. 552(d)); E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351, as amended by E.O. 13286, 68 FR 10619, 3 CFR, 2004 Comp., p. 166; Department of Homeland Security Delegation No. 0170.1, para. 2(80).

§ 136.3 [Amended]

■ 41. In § 136.3, remove the text “NPFC MS 7100, U.S. Coast Guard, 4200 Wilson Blvd., Suite 1000, Arlington, VA 20598–7100” and add, in its place, the text “U.S. Coast Guard Stop 7605, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7605”.

§ 136.5 [Amended]

■ 42. In § 136.5(b), remove the text “NPFC MS 7100, U.S. Coast Guard, 4200 Wilson Blvd., Suite 1000, Arlington, VA 20598–7100” and add, in its place, the text “U.S. Coast Guard Stop 7605, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7605”.

§ 136.101 [Amended]

■ 43. In § 136.101(b), remove the text “NPFC MS 7100, U.S. Coast Guard, 4200 Wilson Blvd., Suite 1000, Arlington, VA 20598–7100” and add, in its place, the text “U.S. Coast Guard Stop 7605, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7605”.

PART 137—OIL SPILL LIABILITY: STANDARDS FOR CONDUCTING ALL APPROPRIATE INQUIRIES UNDER THE INNOCENT LAND-OWNER DEFENSE

■ 44. The authority citation for part 137 continues to read as follows:

Authority: 33 U.S.C. 2703(d)(4); Sec. 1512 of the Homeland Security Act of 2002, Pub. L. 107–296, Title XV, Nov. 25, 2002, 116 Stat. 2310 (6 U.S.C. 552(d)); Department of Homeland Security Delegation No. 14000.

§ 137.15 [Amended]

■ 45. In § 137.15, remove the text “4200 Wilson Boulevard, Suite 1000, Arlington, VA” and add, in its place, the text “NPFC CV, U.S. Coast Guard Stop 7605, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7605”.

PART 138—FINANCIAL RESPONSIBILITY FOR WATER POLLUTION (VESSELS) AND OPA 90 LIMITS OF LIABILITY (VESSELS, DEEPWATER PORTS AND ONSHORE FACILITIES)

■ 46. The authority citation for part 138 continues to read as follows:

Authority: 33 U.S.C. 2704, 2716, 2716a; 42 U.S.C. 9608, 9609; 6 U.S.C. 552; E.O. 12580, Sec. 7(b), 3 CFR, 1987 Comp., p. 193; E.O. 12777, Secs. 4 and 5, 3 CFR, 1991 Comp., p. 351, as amended by E.O. 13286, Sec. 89, 3 CFR, 2004 Comp., p. 166, and by E.O. 13638, Sec. 1, 3 CFR, 2014 Comp., p. 227; Department of Homeland Security Delegation Nos. 0170.1 and 5110, Revision 01. Section 138.30 also issued under the authority of 46 U.S.C. 2103 and 14302.

§ 138.45 [Amended]

■ 47. In § 138.45(a), remove the text “NPFC CV MS 7100, U.S. Coast Guard, 4200 Wilson Blvd., Suite 1000, Arlington, VA 20598–7100, telephone 202–872–6130, fax 703–872–6123” and add, in its place, the text “U.S. Coast Guard Stop 7605, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7605, telephone 202–795–6130, fax 202–795–6123”.

PART 151—VESSELS CARRYING OIL, NOXIOUS LIQUID SUBSTANCES, GARBAGE, MUNICIPAL OR COMMERCIAL WASTE, AND BALLAST WATER

■ 48. The authority citation for part 151 continues to read as follows:

Authority: 33 U.S.C. 1321, 1902, 1903, 1908; 46 U.S.C. 6101; Pub. L. 104–227 (110 Stat. 3034); Pub. L. 108–293 (118 Stat. 1063), sec. 623; E.O. 12777, 3 CFR, 1991 Comp. p. 351; DHS Delegation No. 0170.1, sec. 2(77).

§ 151.1510 [Amended]

■ 49. In § 151.1510(a)(3)(ii), remove the text “Stop 7410, 4200 Wilson Boulevard, Suite 400, Arlington, VA 20598–7410” and add, in its place, the text “Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7430”.

§ 151.2025 [Amended]

■ 50. In § 151.2025(b), remove the text “Stop 7410, 4200 Wilson Boulevard, Suite 400, Arlington, VA 20598–7410” and add, in its place, the text “Stop

7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7430”.

§ 151.2026 [Amended]

■ 51. In § 151.2026(b), remove the text “Stop 7410, 4200 Wilson Boulevard, Suite 400, Arlington, VA 20598–7410” and add, in its place, the text “Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7430”.

PART 155—OIL OR HAZARDOUS MATERIAL POLLUTION PREVENTION REGULATIONS FOR VESSELS

■ 52. The authority citation for part 155 continues to read as follows:

Authority: 3 U.S.C. 301 through 303; 33 U.S.C. 1225, 1231, 1321(j), 1903(b), 2735; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; Department of Homeland Security Delegation No. 0170.1. Section 155.480 also issued under section 4110(b) of Pub. L. 101.380.

§ 155.480 [Amended]

■ 53. In § 155.480(b)(2)(iii), after the text “46 CFR 39.2003(b)(1)”, add the text “, (2), and (3)”.

■ 54. Amend § 155.1065 as follows:

■ a. In paragraph (a), remove the text “<http://evrp.uscg.mil> or by mail to Commandant (CG–CVC–1),” and add, in its place, the text “<http://homeport.uscg.mil/vrpexpress> or by mail to Commandant (CG–MER),”; and

■ b. Revise paragraph (h).

The revision reads as follows:

§ 155.1065 Procedures for plan submission, approval, requests for acceptance of alternative planning criteria, and appeal.

*(h) Within 21 days of notification that a plan is not approved, the vessel owner or operator may appeal that determination to the Director of Incident Management and Preparedness Policy (CG–5RI). This appeal must be submitted in writing to Commandant (CG–5RI), Attn: Director of Incident Management and Preparedness Policy, U.S. Coast Guard Stop 7516, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7516.

■ 55. Amend § 155.1070 as follows:

■ a. In paragraph (f) introductory text, remove the text “Commandant (CG–CVC), Attn: Office of Commercial Vessel Compliance, U.S. Coast Guard Stop 7501, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7501” and add, in its place, the text “Commandant (CG–MER), Attn: Vessel Response Plans, U.S. Coast Guard Stop 7516, 2703 Martin Luther King Jr.

Avenue SE., Washington, DC 20593–7516”; and

■ b. Revise paragraph (g).

The revision reads as follows:

§ 155.1070 Procedures for plan review, revision, amendment, and appeal.

(g) Within 21 days of notification that a plan is not approved, the vessel owner or operator may appeal that determination to the Director of Incident Management and Preparedness Policy (CG–5RI). This appeal must be submitted in writing to Commandant (CG–5RI), Attn: Director of Incident Management and Preparedness Policy, U.S. Coast Guard Stop 7516, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7516.

§ 155.4025 [Amended]

■ 56. Amend § 155.4025, in paragraph (1)(iii) of the definition of “Contract or other approved means”, by removing the text “Commandant, Director of Prevention Policy (CG–54)” and adding, in its place, the text “Assistant Commandant for Response Policy (CG–5R)”.

§ 155.4055 [Amended]

■ 57. Amend § 155.4055 as follows:

■ a. In paragraph (d), remove the text “Commandant, Director of Prevention Policy (CG–5P)” and add, in its place, the text “Assistant Commandant for Response Policy (CG–5R)”; and remove the text “District to the Commandant (CG–5P)” and add, in its place, the text “District, to the Assistant Commandant (CG–5R)”; and

■ b. In paragraph (f), remove the text “Commandant, Director of Prevention Policy (CG–5P)” and add, in its place, the text “Assistant Commandant for Response Policy (CG–5R)”.

§ 155.5035 [Amended]

■ 58. In § 155.5035(k) introductory text, remove the text “Commandant (CG–CVC), Office of Commercial Vessel Compliance” and add, in its place, the text “Commandant (CG–MER), Office of Marine Environmental Response Policy”.

§ 155.5061 [Amended]

■ 59. Amend § 155.5061 as follows:

■ a. In paragraph (a), remove the text “Commandant (CG–CVC)” and add, in its place, the text “(CG–MER), Office of Marine Environmental Response Policy”; and

■ b. In paragraphs (c) introductory text and (f), remove the text “(CG–CVC)” and add, in its place, the text “(CG–MER)”.

§ 155.5065 [Amended]

■ 60. In § 155.5065(a), remove the text “(CG-CVC-1), Attn: Vessel Response Plans, U.S. Coast Guard Stop 7501, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593-7501” and add, in its place, the text “(CG-MER), Attn: Vessel Response Plans, U.S. Coast Guard Stop 7516, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593-7516”.

§ 155.5067 [Amended]

■ 61. In § 155.5067(a), following the text “being considered by Commandant” remove the text “(CG-CVC), Office of Commercial Vessel Compliance” and add, in its place, the text “(CG-MER), Office of Marine Environmental Response Policy”; and following the text “received by Commandant” remove the text “(CG-CVC)” and add, in its place, the text “(CG-MER)”.

■ 62. Amend § 155.5075 as follows:

■ a. In paragraph (a) introductory text, remove the text “(CG-5PC), Attn: Director of Inspections and Compliance, U.S. Coast Guard Stop 7501, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593-7501” and add, in its place, the text “(CG-5RI), Attn: Director of Incident Management and Preparedness Policy, U.S. Coast Guard Stop 7516, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593-7516”; and

■ b. Revise paragraph (b).

The revision reads as follows:

§ 155.5075 Appeal procedures.

* * * * *

(b) Within 21 days of notification that a VRP is not approved, the vessel owner or operator may appeal that determination to the Director of Incident Management and Preparedness Policy (CG-5RI). This appeal must be submitted in writing to Commandant (CG-5RI), Attn: Director of Incident Management and Preparedness Policy, U.S. Coast Guard Stop 7516, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593-7516.

Appendix B to Part 155 [Amended]

■ 63. In section 6.5 of appendix B, remove the text “(CG-CVC-1), Attn: Vessel Response Plans, U.S. Coast

Guard Stop 7501, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593-7501” and add, in its place, the text “(CG-MER), Attn: Vessel Response Plans, U.S. Coast Guard Stop 7516, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593-7516”.

PART 157—RULES FOR THE PROTECTION OF THE MARINE ENVIRONMENT RELATING TO TANK VESSELS CARRYING OIL IN BULK

■ 64. The authority citation for part 157 continues to read as follows:

Authority: 33 U.S.C. 1903; 46 U.S.C. 3703, 3703a (note); Department of Homeland Security Delegation No. 0170.1. Subparts G, H, and I are also issued under section 4115(b), Pub. L. 101-380, 104 Stat. 520; Pub. L. 104-55, 109 Stat. 546.

§ 157.100 [Amended]

■ 65. In § 157.100(b), remove the text “Stop 7410, 4200 Wilson Boulevard, Suite 400, Arlington, VA 20598-7410” and add, in its place, the text “Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593-7430.”.

§ 157.200 [Amended]

■ 66. In § 157.200(b), remove the text “Stop 7410, 4200 Wilson Boulevard, Suite 400, Arlington, VA 20598-7410” and add, in its place, the text “Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593-7430”.

PART 159—MARINE SANITATION DEVICES

■ 67. The authority citation for part 159 continues to read as follows:

Authority: 33 U.S.C. 1322(b)(1); 49 CFR 1.45(b). Subpart E also issued under authority of sec. 1(a)(4), Pub. L. 106-554, 114 Stat. 2763; Department of Homeland Security Delegation No. 0170.1.

§ 159.4 [Amended]

■ 68. In § 159.4(a), remove the text “Stop 7410, 4200 Wilson Boulevard, Suite 400, Arlington, VA 20598-7410” and add, in its place, the text “Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593-7430”.

§ 159.12 [Amended]

■ 69. In § 159.12(c) introductory text, remove the text “Stop 7410, 4200 Wilson Boulevard, Suite 400, Arlington, VA 20598-7410” and add, in its place, the text “Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593-7430”.

§ 159.15 [Amended]

■ 70. In § 159.15(a) introductory text and (c), remove each instance of the text “Stop 7410, 4200 Wilson Boulevard, Suite 400, Arlington, VA 20598-7410” and add, in their place, the text “Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593-7430”.

§ 159.17 [Amended]

■ 71. In § 159.17(a), remove the text “Stop 7410, 4200 Wilson Boulevard, Suite 400, Arlington, VA 20598-7410” and add, in its place, the text “Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593-7430”.

§ 159.19 [Amended]

■ 72. In § 159.19(a), remove the text “Stop 7410, 4200 Wilson Boulevard, Suite 400, Arlington, VA 20598-7410” and add, in its place, the text “Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593-7430”.

PART 161—VESSEL TRAFFIC MANAGEMENT

■ 73. The authority citation for part 161 continues to read as follows:

Authority: 33 U.S.C. 1223, 1231; 46 U.S.C. 70114, 70119; Pub. L. 107-295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 74. Amend § 161.12(c) as follows:

■ a. Remove the text “Table 161.12(c)” and add, in its place, the text “Table 1 to § 161.12(c)”;

■ b. Revise the table.

The revision reads as follows:

§ 161.12 Vessel operating requirements.

* * * * *

(c) * * *

TABLE 1 TO § 161.12(c)—VTS AND VMRS CENTERS, CALL SIGNS/MMSI, DESIGNATED FREQUENCIES, AND MONITORING AREAS

Designation	VTS and VMRS Centers	Center call sign and MMSI ¹	Designated frequency (channel designation)—purpose ²	Monitoring area ^{3,4}
(1)	Berwick Bay—	<i>Berwick Traffic</i> 003669950.	156.550 MHz (Ch. 11)	The waters south of 29°45.00' N., west of 91°10.00' W., north of 29°37.00' N., and east of 91°18.00' W.

TABLE 1 TO § 161.12(c)—VTS AND VMRS CENTERS, CALL SIGNS/MMSI, DESIGNATED FREQUENCIES, AND MONITORING AREAS—Continued

Designation	VTS and VMRS Centers	Center call sign and MMSI ¹	Designated frequency (channel designation)—purpose ²	Monitoring area ^{3,4}
(2)	Buzzards Bay—	<i>Buzzards Bay Control</i> ⁵	156.550 MHz (Ch. 11)	The waters east and north of a line drawn from the southern tangent of Sakonnet Point, Rhode Island, in approximate position latitude 41°27.20' N., longitude 71°11.70' W., to the Buzzards Bay Entrance Light in approximate position latitude 41°23.48' N., longitude 71°02.5' W., and then to the southwestern tangent of Cuttyhunk Island, Massachusetts, at approximate position latitude 41°24.60' N., longitude 70°57.00' W., and including all of the Cape Cod Canal to its eastern entrance, except that the area of New Bedford Harbor within the confines (north of) the hurricane barrier, and the passages through the Elizabeth Islands, is not considered to be "Buzzards Bay".
(3)	Houston-Galveston— ..			The navigable waters north of 29°00.00' N., west of 94°20.00' W., south of 29°49.00' N., and east of 95°20.00' W.
(i)		<i>Houston Traffic</i> 003669954.	156.550 MHz (Ch. 11) 156.250 MHz (Ch. 5A)—For Sailing Plans only.	The navigable waters north of a line extending due west from the southernmost end of Exxon Dock #1 (20°43.37' N., 95°01.27' W.).
(ii)		<i>Houston Traffic</i>	156.600 MHz (Ch. 12) 156.250 MHz (Ch. 5A)—For Sailing Plans only.	The navigable waters south of a line extending due west from the southernmost end of Exxon Dock #1 (29°43.37' N., 95°01.27' W.).
(4)	Los Angeles-Long Beach—	<i>San Pedro Traffic</i> 03660465.	156.700 MHz (Ch. 14)	<i>Vessel Movement Reporting System Area:</i> The navigable waters within a 25 nautical mile radius of Point Fermin Light (33°42.30' N., 118°17.60' W.).
(5)	Louisville—	<i>Louisville Traffic</i> 003669732.	156.650 MHz (Ch. 13)	The waters of the Ohio River between McAlpine Locks (Mile 606) and Twelve Mile Island (Mile 593), only when the McAlpine upper pool gauge is at approximately 13.0 feet or above.
(6)	Lower Mississippi River—			
(i)		<i>New Orleans Traffic</i> 0036699952.	156.550 MHz (Ch. 11)	The navigable waters of the Lower Mississippi River below 29°55.30' N., 89°55.60' W. (Saxonholm Light) at 86.0 miles Above Head of Passes (AHP), extending down river to Southwest Pass, and, within a 12 nautical mile radius around 28°54.30' N., 89°25.70' W. (Southwest Pass Entrance Light) at 20.1 miles Below Head of Passes (BHP).
(ii)		<i>New Orleans Traffic</i>	156.600 MHz (Ch. 12)	The navigable waters of the Lower Mississippi River bounded on the north by a line drawn perpendicular on the river at 29°55.50' N., 90°12.77' W. (Upper Twelve Mile Point) at 109.0 miles AHP and on the south by a line drawn perpendicularly at 29°55.30' N., 89°55.60' W. (Saxonholm Light) at 86.0 miles AHP.
(iii)		<i>New Orleans Traffic</i>	156.250 MHz (Ch. 05A)	The navigable waters of the Lower Mississippi River below 30°38.70' N., 91°17.50' W. (Port Hudson Light) at 254.5 miles AHP bounded on the south by a line drawn perpendicular on the river at 29°55.50' N., 90°12.77' W. (Upper Twelve Mile Point) at 109.0 miles AHP.
(7)	New York—			

TABLE 1 TO § 161.12(c)—VTS AND VMRS CENTERS, CALL SIGNS/MMSI, DESIGNATED FREQUENCIES, AND MONITORING AREAS—Continued

Designation	VTS and VMRS Centers	Center call sign and MMSI ¹	Designated frequency (channel designation)—purpose ²	Monitoring area ^{3,4}
(i)		<i>New York Traffic</i> 003669951.	156.550 MHz (Ch. 11)—For Sailing Plans only. 156.600 MHz (Ch. 12)—For vessels at anchor.	The area consists of the navigable waters of the Lower New York Bay bounded on the east by a line drawn from Norton Point to Breezy Point; on the south by a line connecting the entrance buoys at the Ambrose Channel, Swash Channel, and Sandy Hook Channel to Sandy Hook Point; and on the southeast including the waters of Sandy Hook Bay south to a line drawn at latitude 40°25.00' N.; then west in the Raritan Bay to the Raritan River Railroad Bridge, then north into waters of the Arthur Kill and Newark Bay to the Lehigh Valley Draw Bridge at latitude 40°41.90' N.; and then east including the waters of the Kill Van Kull (KVK) and the Upper New York Bay north to a line drawn east-west from the Holland Tunnel ventilator shaft at latitude 40°43.70' N., longitude 74°01.60' W., in the Hudson River; and then continuing east including the waters of the East River to the Throgs Neck Bridge, excluding the Harlem River.
(ii)		<i>New York Traffic</i>	156.700 MHz (Ch. 14)	The navigable waters of the Lower New York Bay west of a line drawn from Norton Point to Breezy Point; and north of a line connecting the entrance buoys of Ambrose Channel, Swash Channel, and Sandy Hook Channel, to Sandy Hook Point; on the southeast including the waters of the Sandy Hook Bay south to a line drawn at latitude 40°25.00' N.; then west into the waters of Raritan Bay East Reach to a line drawn from Great Kills Light south through Raritan Bay East Reach LGB #14 to Comfort Point, New Jersey; then north including the waters of the Upper New York Bay south of 40°42.40' N. (Brooklyn Bridge) and 40°43.70' N. (Holland Tunnel Ventilator Shaft); west through the KVK into the Arthur Kill north of 40°38.25' N. (Arthur Kill Railroad Bridge); then north into the waters of the Newark Bay, south of 40°41.95' N. (Lehigh Valley Draw Bridge).
(iii)		<i>New York Traffic</i>	156.600 MHz (Ch. 12)	The navigable waters of the Raritan Bay south to a line drawn at latitude 40°26.00' N.; then west of a line drawn from Great Kills Light south through the Raritan Bay East Reach LGB #14 to Point Comfort, New Jersey; then west to the Raritan River Railroad Bridge; and north including the waters of the Arthur Kill to 40°28.25' N. (Arthur Kill Railroad Bridge); including the waters of the East River north of 40°42.40' N. (Brooklyn Bridge) to the Throgs Neck Bridge, excluding the Harlem River.
(8)	Port Arthur—			
(i)		<i>Port Arthur Traffic</i> 003669955.	156.050 MHz (Ch. 01A)	The navigable waters of the Sabine-Neches Canal south of 29°52.70' N.; Port Arthur Canal; Sabine Pass Channel; Sabine Bank Channel; Sabine Outer Bar Channel; the offshore safety fairway; and the ICW from High Island to its intersection with the Sabine-Neches Canal.
(ii)		<i>Port Arthur Traffic</i>	156.275 MHz (Ch. 65A)	The navigable waters of the Neches River; Sabine River; and Sabine-Neches Waterway north of 29°52.70' N.; and the ICW from its intersection with the Sabine River to MM 260.

TABLE 1 TO § 161.12(c)—VTS AND VMRS CENTERS, CALL SIGNS/MMSI, DESIGNATED FREQUENCIES, AND MONITORING AREAS—Continued

Designation	VTS and VMRS Centers	Center call sign and MMSI ¹	Designated frequency (channel designation)—purpose ²	Monitoring area ^{3,4}
(iii)		<i>Port Arthur Traffic</i>	156.675 MHz (Ch. 73) ⁶	The navigable waters of the Calcasieu Channel; Calcasieu River Channel; and the ICW from MM 260 to MM 191.
(9)	Prince William Sound—	<i>Valdez Traffic</i> 003669958.	156.650 MHz (CH. 13)	The navigable waters south of 61°05.00' N., east of 147°20.00' W., north of 60°00.00' N., and west of 146°30.00' W.; and, all navigable waters in Port Valdez.
(10)	Puget Sound— ⁷			
(i)		<i>Seattle Traffic</i> — 003669957.	156.700 MHz (Ch. 14)	The waters of Puget Sound, Hood Canal and adjacent waters south of a line connecting Nodule Point and Bush Point in Admiralty Inlet and south of a line drawn due east from the southernmost tip of Possession Point on Whidbey Island to the shoreline.
(ii)		<i>Seattle Traffic</i> —	156.250 MHz (Ch. 5A)	The U.S. waters of the Strait of Juan de Fuca east of 124°40.00' W. including waters south and east of a line drawn from Church Point on Vancouver Island, to Race Rocks Light, due east to the intersection of the U.S./Canadian border at 48°17.88' N., 123°14.1' W., north-easterly to Hein Bank in position 48°21.094' N., 123°02.672' W., northerly to Cattle Point Light on San Juan Island, along the shoreline to Lime Kiln Light, to Kellett Bluff Light on Henry Island, along the shoreline to the tip of McCracken Point at the northernmost point of Henry Island, to the southernmost point on Stuart Island in position 48°39.46' N., 123°11.08' W., along the shoreline to Turn Point Light, to Sandy Point on Waldron Island, along the shoreline to Point Hammond, to Patos Island Light, to Alden Bank in position 48°50.39' N., 122°52.227' W., then due north to Boundary Bay in position 49°00.125' N., 122°52.228' W., then due east along the international boundary to the shoreline in Semiahmoo Bay line connecting Nodule Point and Bush Point and all waters east of Whidbey Island north of a line drawn due east from the southernmost tip of Possession Point on Whidbey Island to the shoreline.
(iii)		<i>Prince Rupert Traffic</i> — 003160013.	156.725 MHz (Ch. 74)	The waters west of 124°40.00' W. within 12 nautical miles of the coast of Vancouver Island including the waters north of 48°00.00' N., and east of 125°15.00' W.

TABLE 1 TO § 161.12(c)—VTS AND VMRS CENTERS, CALL SIGNS/MMSI, DESIGNATED FREQUENCIES, AND MONITORING AREAS—Continued

Designation	VTS and VMRS Centers	Center call sign and MMSI ¹	Designated frequency (channel designation)—purpose ²	Monitoring area ^{3,4}
(iv)		<i>Victoria Traffic</i> — 003160010.	156.550 MHz (Ch. 11)	The waters of the Strait of Georgia, including Vancouver Harbor, Boundary Pass, and Haro Strait north and west of a line drawn from Church Point on Vancouver Island, to Race Rocks Light, due easterly to the intersection of the U.S./Canadian border at 48°17.883' N., 123°14.1' W., north-easterly to Hein Bank in position 48°21.093' N., 123°02.762' W., northerly to Cattle Point Light on San Juan Island, along the shoreline to Lime Kiln Light, to Kellett Bluff Light on Henry Island, along the shoreline to the tip of McCracken Point at the northernmost point of Henry Island, to the southernmost point on Stuart Island in position 48°39.467' N., 123°11.083' W., along the shoreline to Turn Point Light, to Sandy Point on Waldron Island, along the shoreline to Point Hammond, to Patos Island Light, to Alden Bank in position 48°50.389' N., 122°52.227' W., then due north to Boundary Bay in position 49°00.125' N., 122°52.227' W., then due east along the international boundary to the shoreline in Semiahmoo Bay.
(11)	San Francisco—	<i>San Francisco Traffic</i> 003669956.	156.700 MHz (Ch. 14)	The navigable waters of the San Francisco Off-shore Precautionary Area, the navigable waters shoreward of the San Francisco Off-shore Precautionary Area east of 122°42.00' W. and north of 37°40.00' N. extending eastward through the Golden Gate, and the navigable waters of San Francisco Bay and as far east as the port of Stockton on the San Joaquin River, as far north as the port of Sacramento on the Sacramento River.
(i)				
(ii)		<i>San Francisco Traffic</i> ..	156.600 MHz (Ch. 12)	The navigable waters within a 38 nautical mile radius of Mount Tamalpais (37°55.80' N., 122°34.60' W.) west of 122°42.00' W. and south of 37°40.00' N. and excluding the San Francisco Offshore Precautionary Area.
(12)	St. Mary's River—	<i>Soo Traffic</i> 003669953	156.600 MHz (Ch. 12)	The waters of the St. Mary's River and lower Whitefish Bay from 45°57.00' N. (De Tour Reef Light) to the south, to 46°38.70' N. (Ile Parisienne Light) to the north, except the waters of the St. Mary's Falls Canal and to the east along a line from La Pointe to Sims Point, within Potagannissing Bay and Worsley Bay.

Notes:

¹ Maritime Mobile Service Identifier (MMSI) is a unique nine-digit number assigned that identifies ship stations, ship earth stations, coast stations, coast earth stations, and group calls for use by a digital selective calling (DSC) radio, an INMARSAT ship earth station or AIS. AIS requirements are set forth in § 161.21. The requirements set forth in §§ 161.21 and 164.46 of this subchapter apply in those areas denoted with an MMSI number, except for Louisville and Los Angeles/Long Beach.

² In the event of a communication failure, difficulties or other safety factors, the Center may direct or permit a user to monitor and report on any other designated monitoring frequency or the bridge-to-bridge navigational frequency, 156.650 MHz (Channel 13) or 156.375 MHz (Channel 67), to the extent that doing so provides a level of safety beyond that provided by other means. The bridge-to-bridge navigational frequency, 156.650 MHz (Ch. 13) is used in certain monitoring areas where the level of reporting does not warrant a designated frequency.

³ All geographic coordinates (latitude and longitude) are expressed in North American Datum of 1983 (NAD 83).

⁴ Some monitoring areas extend beyond navigable waters. Although not required, users are strongly encouraged to maintain a listening watch on the designated monitoring frequency in these areas. Otherwise, they are required to maintain watch as stated in 47 CFR 80.148.

⁵ In addition to the vessels denoted in § 161.16, requirements set forth in subpart B of this part also apply to any vessel transiting VMRS Buzzards Bay required to carry a bridge-to-bridge radiotelephone by part 26 of this chapter.

⁶ Until otherwise directed, full VTS services will not be available in the Calcasieu Channel, Calcasieu River Channel, and the ICW from MM 260 to MM 191. Vessels may contact Port Arthur Traffic on the designated VTS frequency to request advisories, but are not required to monitor the VTS frequency in this sector.

⁷ A Cooperative Vessel Traffic Service was established by the United States and Canada within adjoining waters. The appropriate Center administers the rules issued by both nations; however, enforces only its own set of rules within its jurisdiction. Note: the bridge-to-bridge navigational frequency, 156.650 MHz (Ch. 13), is not so designated in Canadian waters, therefore users are encouraged and permitted to make passing arrangements on the designated monitoring frequencies.

* * * * *

§ 161.45 [Amended]

■ 75. Amend § 161.45, in Table 161.45(b), as follows:

■ a. Remove the text “Table 161.45(b)” and add, in its place, the text “Table 1 to § 161.45(b)”;

■ b. Remove the text “5” in the Designator column, and add, in its place, the text “5”.

§ 161.50 [Amended]

■ 76. In § 161.50, remove the text “37-55.8’ N., 122-34.6’ W.” and add, in its place, the text “37°55.8’ N., 122°34.6’ W.”.

■ 77. In § 161.55, revise the introductory text and paragraph (a) to read as follows:

§ 161.55 Vessel Traffic Service Puget Sound and the Cooperative Vessel Traffic Service for the Juan de Fuca Region.

The Vessel Traffic Service Puget Sound area consists of the U.S. navigable waters of the Salish Sea from a line drawn from the Washington State coastline at 48°23.133’ N., 124°43.616’ W. on Cape Flattery to the Cape Flattery Light at 48°23.5’ N., 124°44.2’ W. on Tatoosh Island, due west to the U.S. Territorial Sea Boundary; thence northward along the U.S. Territorial Sea Boundary to its intersection with the U.S./Canada International Boundary; thence east along the U.S./Canada International Boundary to 49°00.1’ N., 122°45.3’ W. (International Boundary Range C Rear Light).

(a) Vessel Traffic Service Puget Sound participates in a U.S./Canadian Cooperative Vessel Traffic Service (CVTS) to jointly manage vessel traffic in the Juan de Fuca Region. The CVTS for the Juan de Fuca Region consists of all navigable waters of the Salish Sea, bounded on the northwest by 48°35.749’ N.; and on the southwest by 48°23.5’ N.; and on the west by the rhumb line joining 48°35.749’ N., 124°47.5’ W. with 48°23.5’ N., 124°48.616’ W.; and on the northeast by a line drawn along 49° N. from Vancouver Island to Semiahmoo Bay; and on the southeast, by a line drawn from McCurdy Point on the Quimper Peninsula to Point Partridge on Whidbey Island. Canadian and United States Vessel Traffic Centers (Prince Rupert, B.C., Canada; Vancouver, B.C., Canada; and Seattle, WA) manage traffic within the CVTS area irrespective of the International Boundary.

* * * * *

PART 162—INLAND WATERWAYS NAVIGATION REGULATIONS

■ 78. The authority citation for part 162 continues to read as follows:

Authority: 33 U.S.C. 1231; Department of Homeland Security Delegation No. 0170.1.

§ 162.205 [Amended]

■ 79. Amend § 162.205 as follows:

■ a. In paragraph (a)(3)(i), remove the text “part 80” and add, in its place, the text “part 83”.

■ b. In paragraph (b)(2)(i), remove the text “part 80, of this Chapter” and add, in its place, the text “part 83 of this chapter”.

PART 164—NAVIGATION SAFETY REGULATIONS

■ 80. The authority citation for part 164 continues to read as follows:

Authority: 33 U.S.C. 1222(5), 1223, 1231; 46 U.S.C. 2103, 3703; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1. Sec. 164.13 also issued under 46 U.S.C. 8502. Sec. 164.46 also issued under 46 U.S.C. 70114 and Sec. 102 of Pub. L. 107-295. Sec. 164.61 also issued under 46 U.S.C. 6101.

§ 164.33 [Amended]

■ 81. In § 164.33(a)(3)(ii), remove the text “the U.S. Army Corps of Engineers, or”.

§ 164.46 [Amended]

■ 82. In the note to § 164.46(b), at the end of the paragraph, add the sentence “Fishing industry vessels include fishing vessels, fish processing vessels, and fish tender vessels as defined in 46 U.S.C. 2101.”.

§ 164.72 [Amended]

■ 83. In § 164.72(b)(2)(i)(C), remove the text “the ACOE or”.

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

§ 165.100 [Amended]

■ 85. Amend § 165.100(d)(5)(i) as follows:

■ a. Remove the text “41°-27.2’” and add, in its place, the text “41°27.2’”;

■ b. Remove the text “70°-11.7’” and add, in its place, the text “71°11.7’”;

■ c. Remove the text “41°-23.5’” and add, in its place, the text “41°23.48’”;

■ d. Remove the text “71°-02.0’” and add, in its place, the text “71°02.5’”;

■ e. Remove the text “41°-24.6’” and add, in its place, the text “41°24.6’”;

■ f. Remove the text “70°-57.0’” and add, in its place, the text “70°57.0’”.

§ 165.T0704 [Removed]

■ 86a. Remove § 165.T0704.

■ 86b. Add § 165.704 to read as follows:

§ 165.704 Safety Zone: Savannah River, Savannah, Georgia.

(a) *Location.* The following area is a safety zone: Two hundred foot radius around Garden City Terminal, approximate position 32 degrees 8 minutes, N, 81 degrees 9.5 minutes W, and around all cargo ships loaded with military equipment and transiting the Savannah River.

(b) *Enforcement date.* This regulation was enforceable beginning at 12 p.m. on December 14, 1990.

(c) *Regulation.* In accordance with the general regulations in § 165.23, entry into the zone is subject to the following requirements.

(1) All persons and vessels in the vicinity of the safety zone shall immediately obey any direction or order of the Captain of the Port or a representative of the Captain of the Port.

(2) The “representative of the Captain of the Port” is any Coast Guard commissioned, warrant or petty officer who has been designated by the Captain of the Port, Savannah, GA to act on his behalf. A representative of the Captain of the Port may be contacted on board any Coast Guard vessel assigned to enforce the safety zone.

(3) Before entering the safety zone, a vessel operator shall contact the Captain of the Port or a representative of the Captain of the Port to determine what restrictions, if any, have been imposed on vessels in the safety zone. The Captain of the Port may be contacted by telephone via the Command Duty Officer at 912-652-4353. Coast Guard vessels assisting in the enforcement of the safety zone may be contacted on VHF-FM channels 13 or 16, or vessel operators may determine restrictions in effect for the safety zone by coming alongside a Coast Guard vessel patrolling the perimeter of the safety zone.

(4) The Captain of the Port will issue a Marine Safety Information Broadcast Notice to Mariners to Notify the maritime community of the safety zone and restrictions imposed.

§ 165.766 [Removed]

■ 87. Remove § 165.766.

PART 174—STATE NUMBERING AND CASUALTY REPORTING SYSTEMS

- 88. The authority citation for part 174 continues to read as follows:

Authority: 46 U.S.C. 6101 and 12302; Department of Homeland Security Delegation No. 0170.1 (92).

- 89. Revise § 174.123 to read as follows:

§ 174.123 Annual report of vessels.

Before March 1 of each year, each State that has an approved numbering system must prepare and submit Coast Guard Form CGHQ-3923 to the Coast Guard.

PART 181—MANUFACTURER REQUIREMENTS

- 90. The authority citation for part 181 continues to read as follows:

Authority: 46 U.S.C. 4302; Department of Homeland Security Delegation No. 0170.1 (92).

§ 181.3 [Amended]

- 91. In § 181.3, remove the definition of “Model year”.

Title 46—Shipping and Transportation**PART 4—MARINE CASUALTIES AND INVESTIGATIONS**

- 92. The authority citation for part 4 continues to read as follows:

Authority: 33 U.S.C. 1231; 43 U.S.C. 1333; 46 U.S.C. 2103, 2303a, 2306, 6101, 6301, and 6305; 50 U.S.C. 198; Department of Homeland Security Delegation No. 0170.1. Subpart 4.40 issued under 49 U.S.C. 1903(a)(1)(E).

§ 4.07–10 [Amended]

- 93. Amend § 4.07–10(a)(4) by removing the text “on Form CG-2636, report of violation of navigation laws”.

PART 28—REQUIREMENTS FOR COMMERCIAL FISHING INDUSTRY VESSELS

- 94. The authority citation for part 28 continues to read as follows:

Authority: 46 U.S.C. 3316, 4502, 4505, 4506, 6104, 8103, 10603; Department of Homeland Security Delegation No. 0170.1.

- 95. Revise § 28.80(d)(1) to read as follows:

§ 28.80 Report of casualty.

* * * * *

(d) * * *

(1) Verisk Insurance Solutions, ISO Claim Search® Solutions, 545 Washington Boulevard, Jersey City, NJ 07310.

* * * * *

- 96. Revise § 28.1105(a) to read as follows:

§ 28.1105 Request for a waiver.

(a) Vessel owners, operators, or employers who desire a waiver of citizenship requirements from the Coast Guard must submit a written request to the Commandant (CG-CVC), United States Coast Guard Headquarters, Stop 7501, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7501.

* * * * *

PART 31—INSPECTION AND CERTIFICATION

- 97. The authority citation for part 31 continues to read as follows:

Authority: 33 U.S.C. 1321(j); 46 U.S.C. 2103, 3205, 3306, 3307, 3703; 46 U.S.C. Chapter 701; 49 U.S.C. 5103, 5106; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; Department of Homeland Security Delegation No. 0170.1. Section 31.10–21 also issued under the authority of Sect. 4109, Pub. L. 101–380, 104 Stat. 515.

§ 31.10–5 [Amended]

- 98. Amend § 31.10–5(a) introductory text by removing the text “Stop 7410, 4200 Wilson Boulevard Suite 400, Arlington, VA 20598–7410” and adding, in its place, the text “Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7430”.

PART 39—VAPOR CONTROL SYSTEMS

- 99. The authority citation for part 39 continues to read as follows:

Authority: 33 U.S.C. 1225, 1231; 42 U.S.C. 7511b(f)(2); 46 U.S.C. 3306, 3703, 3715(b); E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

- 100. In § 39.1003, revise the definition of “Marine Safety Center (MSC)” to read as follows:

§ 39.1003 Definitions—TB/ALL.

* * * * *

Marine Safety Center (MSC) means Commanding Officer, Marine Safety Center, U.S. Coast Guard, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593 for visitors. Send all mail to Commanding Officer (MSC), Attn: Marine Safety Center, U.S. Coast Guard Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7430.

* * * * *

§ 39.2007 [Amended]

- 101. Amend § 39.2007 as follows:

- a. In paragraph (e), remove the text “39.2009(c)” and add, in its place, the text “39.2009(a)(3)”; and
 ■ b. In paragraph (f), remove the text “39.2009(d)” and add, in its place, the text “39.2009(a)(4)”.

PART 44—SPECIAL SERVICE LIMITED DOMESTIC VOYAGES

- 102. The authority citation for part 44 continues to read as follows:

Authority: 46 U.S.C. 5101–5116; Department of Homeland Security Delegation No. 0170.1.

- 103. Revise § 44.320(a) to read as follows:

§ 44.320 Submission of plans and calculations.

* * * * *

(a) Commanding Officer, Marine Safety Center, U.S. Coast Guard, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593, for visitors. Send all mail to Commanding Officer (MSC), Attn: Marine Safety Center, U.S. Coast Guard Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7430; or

* * * * *

PART 50—GENERAL PROVISIONS

- 104. The authority citation for part 50 continues to read as follows:

Authority: 43 U.S.C. 1333; 46 U.S.C. 3306, 3703; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1; Section 50.01–20 also issued under the authority of 44 U.S.C. 3507.

- 105. Revise § 50.10–23 to read as follows:

§ 50.10–23 Marine Safety Center.

The term *Marine Safety Center* refers to the Commanding Officer, Marine Safety Center, U.S. Coast Guard, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593 for visitors. Send all mail to Commanding Officer (MSC), Attn: Marine Safety Center, U.S. Coast Guard Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7430, in a written or electronic format. Information for submitting the VSP electronically can be found at <http://www.uscg.mil/HQ/MSC>.

PART 58—MAIN AND AUXILIARY MACHINERY AND RELATED SYSTEMS

- 106. The authority citation for part 58 continues to read as follows:

Authority: 43 U.S.C. 1333; 46 U.S.C. 3306, 3703; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

- 107. Amend § 58.50–5 as follows:

■ a. In paragraph (a)(2), remove the text “Table 58.50–5(a)” and add, in its place, the text “Table 1 to § 58.50–5(a)”;

■ b. Revise the table in paragraph (a).
The revision reads as follows:

§ 58.50–5 Gasoline fuel tanks.

(a) * * *

TABLE 1 TO § 58.50–5(a)

Material	ASTM specification (all incorporated by reference; see 46 CFR 58.03–1)	Thickness in inches and gage numbers ¹ vs. tank capacities for—		
		1- through 80-gallon tanks	More than 80- and not more than 150-gallon tanks	Over 150-gallon tanks ²
Aluminum ⁵	B 209, Alloy 5086 ⁶	0.250 (USSG 3)	0.250 (USSG 3)	0.250 (USSG 3).
Nickel-copper	B 127, Hot rolled sheet or plate	0.037 (USSG 20) ³ ...	0.050 (USSG 18)	0.107 (USSG 12).
Copper-nickel	B 122, Alloy No. 5	0.045 (AWG 17)	0.057 (AWG 15)	0.128 (AWG 8).
Copper	B 152, Type ETP	0.057 (AWG 15)	0.080 (AWG 12)	0.182 (AWG 5).
Copper-silicon	B 96, alloys C65100 and C65500	0.050 (AWG 16)	0.064 (AWG 14)	0.144 (AWG 7).
Steel or iron ⁴		0.0747 (MfgStd 14) ...	0.1046 (MfgStd 12) ...	0.179 (MfgStd 7).

Notes:

¹ Gauges used are U.S. standard “USSG” for aluminum and nickel-copper; “AWG” for copper, copper-nickel and copper-silicon; and “MfgStd” for steel.

² Tanks over 400 gallons will be designed with a factor of safety of four on the ultimate strength of the material used with a design head of not less than 4 feet of liquid above the top of the tank.

³ Nickel-copper not less than 0.031 inch (USSG 22) may be used for tanks up to a 30-gallon capacity.

⁴ Fuel tanks constructed of iron or steel, which is less than 3/16-inch thick must be galvanized inside and outside by the hot dip process.

⁵ Anodic to most common metals. Avoid dissimilar metal contact with tank body.

⁶ And other alloys acceptable to the Commandant.

* * * * *

■ 108. Amend § 58.50–10 as follows:
■ a. In paragraph (a)(2), remove the text “Table 58.50–10(a)” and add, in its

place, the text “Table 1 to § 58.50–10(a)”;

■ b. Revise the table in paragraph (a).
The revision reads as follows:

§ 58.50–10 Diesel fuel tanks.

(a) * * *

TABLE 1 TO § 58.50–10(a)

Material	ASTM specification (all incorporated by reference; see 46 CFR 58.03–1)	Thickness in inches and gage numbers ¹ vs. tank capacities for—		
		1- through 80-gallon tanks	More than 80- and not more than 150-gallon tanks	Over 150-gallon tanks ²
Aluminum ⁵	B 209, Alloy 5086 ⁶	0.250 (USSG 3)	0.250 (USSG 3)	0.250 (USSG 3).
Nickel-copper	B 127, Hot rolled sheet or plate	0.037 (USSG 20) ³ ...	0.050 (USSG 18)	0.107 (USSG 12).
Steel or iron ⁴		0.0747 (MfgStd 14) ...	0.1046 (MfgStd 12) ...	0.179 (MfgStd 7).

Notes:

¹ Gauges used are U.S. standard “USSG” for aluminum and nickel-copper and “MfgStd” for steel or iron.

² Tanks over 400 gallons shall be designed with a factor of safety of four on the ultimate strength of the material used with a design head of not less than 4 feet of liquid above the top of the tank.

³ Nickel-copper not less than 0.031 inch (USSG 22) may be used for tanks up to a 30-gallon capacity.

⁴ For diesel tanks the steel or iron shall not be galvanized on the interior.

⁵ Anodic to most common metals. Avoid dissimilar metal contact with tank body.

⁶ And other alloys acceptable to the Commandant.

* * * * *

PART 63—AUTOMATIC AUXILIARY BOILERS

■ 109. The authority citation for part 63 continues to read as follows:

Authority: 46 U.S.C. 3306, 3703; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

■ 110. Revise the introductory text of § 63.10–1 to read as follows:

§ 63.10–1 Test procedures and certification report.

Two copies of the following items must be submitted. Visitors may deliver them to the Commanding Officer,

Marine Safety Center, U.S. Coast Guard, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593, or they may be transmitted by mail to the Commanding Officer (MSC), Attn: Marine Safety Center, U.S. Coast Guard Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7430, in a written or electronic format. Information for submitting the VSP electronically can be found at <http://www.uscg.mil/HQ/MSC>.

* * * * *

■ 111. Revise § 63.25–9(a) to read as follows:

§ 63.25–9 Incinerators.

(a) *General.* Incinerators installed on or after March 26, 1998 must meet the

requirements of IMO MEPC.76(40) (incorporated by reference; see § 63.05–1). Incinerators in compliance with ISO 13617 (incorporated by reference; see § 63.05–1), are considered to meet IMO MEPC.76(40). Incinerators in compliance with both ASTM F 1323 (incorporated by reference; see § 63.05–1) and Annexes A1–A3 of IMO MEPC.76(40) are considered to meet IMO MEPC.76(40). An application for type approval of shipboard incinerators may be delivered to the Commanding Officer, Marine Safety Center, U.S. Coast Guard, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593, or it may be transmitted by mail to the Commanding Officer (MSC), Attn: Marine Safety Center, U.S. Coast Guard

Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7430.

PART 69—MEASUREMENT OF VESSELS

■ 112. The authority citation for part 69 continues to read as follows:

Authority: 46 U.S.C. 2301, 14103, 14104; Department of Homeland Security Delegation No. 0170.1.

■ 113. Revise § 69.15(a) to read as follows:

§ 69.15 Authorized measurement organizations.

(a) Except as noted under paragraphs (c) and (d) of this section, measurement or remeasurement of all vessels under the Convention Measurement System and Standard and Dual Regulatory Measurement Systems must be performed by an authorized measurement organization meeting the requirements of § 69.27. A current listing of authorized measurement organizations may be obtained from the Commanding Officer, Marine Safety Center (MSC–4), U.S. Coast Guard, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593 or by writing to Commanding Officer (MSC), Attn: Marine Safety Center, U.S. Coast Guard Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7430.

PART 71—INSPECTION AND CERTIFICATION

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

Authority: 33 U.S.C. 1321(j); 46 U.S.C. 2113, 3205, 3306, 3307; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; Department of Homeland Security Delegation No. 0170.1.

■ 115. Revise § 71.65–15(a)(2) to read as follows:

§ 71.65–15 Procedure for submittal of plans.

(a) * * *

(2) The plans may be submitted by visitors directly to the Commanding Officer, Marine Safety Center, U.S. Coast Guard, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593, or transmitted by mail to: Commanding Officer (MSC), Attn: Marine Safety Center, U.S. Coast Guard Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7430, in a written or electronic format. Information for submitting the VSP electronically

can be found at <http://www.uscg.mil/HQ/MSC>. In this case, the plans will be returned directly to the submitter, with a copy of the action being forwarded to the interested Officer in Charge, Marine Inspection.

PART 107—INSPECTION AND CERTIFICATION

■ 116. The authority citation for part 107 continues to read as follows:

Authority: 43 U.S.C. 1333; 46 U.S.C. 3306, 3307; 46 U.S.C. 3316; Department of Homeland Security Delegation No. 0170.1; § 107.05 also issued under the authority of 44 U.S.C. 3507.

■ 117. Revise § 107.317(b) to read as follows:

§ 107.317 Addresses for submittal of plans, specifications, and calculations.

(b) By visitors to the Commanding Officer, Marine Safety Center, U.S. Coast Guard, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593, or by mail to: Commanding Officer (MSC), Attn: Marine Safety Center, U.S. Coast Guard Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7430, in a written or electronic format. Information for submitting the VSP electronically can be found at <http://www.uscg.mil/HQ/MSC>.

PART 110—GENERAL PROVISIONS

■ 118. The authority citation for part 110 is revised to read as follows:

Authority: 43 U.S.C. 1333; 46 U.S.C. 3306, 3307, 3703; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1; § 110.01–2 also issued under 44 U.S.C. 3507. Sections 110.15–1 and 110.25–1 also issued under sec. 617, Pub. L. 111–281, 124 Stat. 2905.

§ 110.15–1 [Amended]

■ 119. In § 110.15–1(b), remove the definitions of “Marine inspector or inspector” and “Qualified person”.

■ 120. Revise § 110.25–3(a)(1) to read as follows:

§ 110.25–3 Procedure for submitting plans.

(a) * * *

(1) By visitors to the Commanding Officer, Marine Safety Center, U.S. Coast Guard, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593, or by mail to: Commanding Officer (MSC), Attn: Marine Safety Center, U.S. Coast Guard Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7430, in a written or electronic format. Information for submitting the

VSP electronically can be found at <http://www.uscg.mil/HQ/MSC>.

PART 111—ELECTRIC SYSTEMS—GENERAL REQUIREMENTS

■ 121. The authority citation for part 111 continues to read as follows:

Authority: 46 U.S.C. 3306, 3703; Department of Homeland Security Delegation No. 0170.1. Section 111.05–20 and Subpart 111.106 also issued under sec. 617, Pub. L. 111–281, 124 Stat. 2905.

§ 111.33–1 [Amended]

■ 122. Amend § 111.33–1 by removing the text “§§ 111.30–11, 111.30–19 and 111.30–21” and adding, in its place, the text “§§ 111.30–11 and 111.30–19”.

§ 111.105–19 [Amended]

■ 123. Amend § 111.105–19 by removing the text “§ 111.105–19” and adding, in its place, the text “§ 111.105–9”.

PART 116—CONSTRUCTION AND ARRANGEMENT

■ 124. The authority citation for part 116 continues to read as follows:

Authority: 46 U.S.C. 2103, 3306; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

■ 125. Revise § 116.202(a) introductory text to read as follows:

§ 116.202 Plans and information required.

(a) Except as provided in § 116.210, the owner of a vessel requesting initial inspection for certification must, prior to the start of construction, submit for approval three copies of the following plans. The plans may be delivered by visitors to the Commanding Officer, Marine Safety Center, U.S. Coast Guard, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593, or transmitted by mail to: Commanding Officer (MSC), Attn: Marine Safety Center, U.S. Coast Guard Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7430, in a written or electronic format. Information for submitting the VSP electronically can be found at <http://www.uscg.mil/HQ/MSC>.

PART 120—ELECTRICAL INSTALLATION

■ 126. The authority citation for part 120 continues to read as follows:

Authority: 46 U.S.C. 2103, 3306; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

§ 120.340 [Amended]

- 127. Amend § 120.340 as follows:
 - a. In paragraph (p), remove the text “Table 120.3340(p)” and add, in its place, the text “Table 1 to § 120.340(p)”;
 - b. In the table in paragraph (p), remove the heading “Table 120.340(p)” and add, in its place, the heading “Table 1 to § 120.340(p)—Conductor Sizes for Amperes—Lengths”.

PART 127—CONSTRUCTION AND ARRANGEMENTS

- 128. The authority citation for part 127 continues to read as follows:

Authority: 46 U.S.C. 3306; sec. 617, Pub. L. 111–281, 124 Stat. 2905; Department of Homeland Security Delegation No. 0170.1.

- 129. Revise § 127.120(b) to read as follows:

§ 127.120 Procedure for submittal of plans.

* * * * *

(b) By visitors to the Commanding Officer, Marine Safety Center, U.S. Coast Guard, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593, or by mail to: Commanding Officer (MSC), Attn: Marine Safety Center, U.S. Coast Guard Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7430, in a written or electronic format. Information for submitting the VSP electronically can be found at <http://www.uscg.mil/HQ/MSC>.

PART 153—SHIPS CARRYING BULK LIQUID, LIQUEFIED GAS, OR COMPRESSED GAS HAZARDOUS MATERIALS

- 130. The authority citation for part 153 continues to read as follows:

Authority: 46 U.S.C. 3703; Department of Homeland Security Delegation No. 0170.1. Section 153.40 issued under 49 U.S.C. 5103. Sections 153.470 through 153.491, 153.1100 through 153.1132, and 153.1600 through 153.1608 also issued under 33 U.S.C. 1903(b).

§ 153.9 [Amended]

- 131. Amend § 153.9(b) introductory text by removing the text “Stop 7410, 4200 Wilson Boulevard, Suite 400, Arlington, VA 20598–7410” and adding, in its place, the text “Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7430”.

PART 154—SAFETY STANDARDS FOR SELF-PROPELLED VESSELS CARRYING BULK LIQUEFIED GASES

- 132. The authority citation for part 154 continues to read as follows:

Authority: 46 U.S.C. 3703, 9101; Department of Homeland Security Delegation No. 0170.1.

§ 154.22 [Amended]

- 133. Amend § 154.22(a) introductory text by removing the text “Stop 7410, 4200 Wilson Boulevard, Suite 400, Arlington, VA 20598–7410” and adding, in its place, the text “Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7430”.

PART 161—ELECTRICAL EQUIPMENT

- 134. The authority citation for part 161 continues to read as follows:

Authority: 46 U.S.C. 3306, 3703, 4302; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

§ 161.010–1 [Amended]

- 135. Amend § 161.010–1(a) by removing the text “4200 Wilson Boulevard, Suite 400, Arlington, VA 22203” and adding, in its place, the text “2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593”.
- 136. Revise § 161.010–4(a) to read as follows:

§ 161.010–4 Procedure for approval.

(a) A request for approval of an automatic floating electric waterlight must be submitted by visitors to the Commanding Officer, Marine Safety Center, U.S. Coast Guard, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593, or transmitted by mail to: Commanding Officer (MSC), Attn: Marine Safety Center, U.S. Coast Guard Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7430, in a written or electronic format. Information for submitting the VSP electronically can be found at <http://www.uscg.mil/HQ/MSC>.

* * * * *

PART 162—ENGINEERING EQUIPMENT

- 137. The authority citation for part 162 continues to read as follows:

Authority: 33 U.S.C. 1321(j), 1903; 46 U.S.C. 3306, 3703, 4104, 4302; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; Department of Homeland Security Delegation No. 0170.1.

- 138. Revise § 162.017–6(a) to read as follows:

§ 162.017–6 Procedure for approval.

(a) *General.* Pressure-vacuum relief valves intended for use on tank vessels must be approved for such use by the Commanding Officer, U.S. Coast Guard Marine Safety Center. Applications for

approval may be delivered by visitors to the Commanding Officer, Marine Safety Center, U.S. Coast Guard, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593, or transmitted by mail to: Commanding Officer (MSC), Attn: Marine Safety Center, U.S. Coast Guard Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7430, in a written or electronic format. Information for submitting the VSP electronically can be found at <http://www.uscg.mil/HQ/MSC>.

* * * * *

- 139. Revise § 162.018–8(a) to read as follows:

§ 162.018–8 Procedure for approval.

(a) *General.* Safety relief valves for use on pressure vessels containing liquefied compressed gases must be approved by the Commanding Officer, U.S. Coast Guard Marine Safety Center. Applications for approval may be delivered by visitors to the Commanding Officer, Marine Safety Center, U.S. Coast Guard, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593, or transmitted by mail to: Commanding Officer (MSC), Attn: Marine Safety Center, U.S. Coast Guard Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7430, in a written or electronic format. Information for submitting the VSP electronically can be found at <http://www.uscg.mil/HQ/MSC>.

* * * * *

- 140. Revise § 162.050–7(a) to read as follows:

§ 162.050–7 Approval procedures.

(a) An application for approval of equipment under this subpart must either be delivered by visitors to the Commanding Officer, Marine Safety Center, U.S. Coast Guard, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593, or transmitted by mail to: Commanding Officer (MSC), Attn: Marine Safety Center, U.S. Coast Guard Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7430, in a written or electronic format. Information for submitting the VSP electronically can be found at <http://www.uscg.mil/HQ/MSC>.

* * * * *

§ 162.060–10 [Amended]

- 141. Amend § 162.060–10(a) introductory text and (b)(1) by removing the text “Stop 7410, 4200 Wilson Boulevard, Suite 400, Arlington, VA 20598–7410” and adding, in its place, the text “Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7430”.

§ 162.060–14 [Amended]

■ 142. Amend § 162.060–14(b) by removing the text “Stop 7410, 4200 Wilson Boulevard, Suite 400, Arlington, VA 20598–7410” and adding, in its place, the text “Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7430”.

§ 162.060–42 [Amended]

■ 143. Amend § 162.060–42(a)(3) and (g) by removing the text “Stop 7410, 4200 Wilson Boulevard, Suite 400, Arlington, VA 20598–7410” and adding, in its place, the text “Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7430”.

PART 170—STABILITY REQUIREMENTS FOR ALL INSPECTED VESSELS

■ 144. The authority citation for part 170 continues to read as follows:

Authority: 43 U.S.C. 1333; 46 U.S.C. 2103, 3306, 3703; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

§ 170.010 [Amended]

■ 145. Amend § 170.010 by removing the text “Stop 7410, 4200 Wilson Boulevard, Suite 400, Arlington, VA 20598–7410” and adding, in its place, the text “Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7430”.

■ 146. Revise § 170.100(b) to read as follows:

§ 170.100 Addresses for submittal of plans and calculations.

* * * * *

(b) By visitors to the Commanding Officer, Marine Safety Center, U.S. Coast Guard, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593, or by mail to: Commanding Officer (MSC), Attn: Marine Safety Center, U.S. Coast Guard Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7430, in a written or electronic format. Information for submitting the VSP electronically can be found at <http://www.uscg.mil/HQ/MSC>.

PART 177—CONSTRUCTION AND ARRANGEMENT

■ 147. The authority citation for part 170 continues to read as follows:

Authority: 46 U.S.C. 2103, 3306; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

§ 177.202 [Amended]

■ 148. Amend § 177.202(d) by removing the text “Stop 7410, 4200 Wilson Boulevard, Suite 400, Arlington, VA

20598–7410” and adding, in its place, the text “Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7430”.

■ 149. Revise § 177.410(b)(5) to read as follows:

§ 177.410 Structural fire protection.

* * * * *

(b) * * *

(5) Specific laminate schedules, regardless of resin type, that have an ASTM E–84 flame spread rating of not more than 100 may be considered as equivalent to the requirement in this section to use a fire retardant resin. Requests for qualifying a specific laminate schedule as a fire retardant for use in a particular vessel may be submitted for consideration by visitors to the Commanding Officer, Marine Safety Center, U.S. Coast Guard, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593, or by mail to: Commanding Officer (MSC), Attn: Marine Safety Center, U.S. Coast Guard Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7430, in a written or electronic format. Information for submitting the VSP electronically can be found at <http://www.uscg.mil/HQ/MSC>.

* * * * *

PART 182—MACHINERY INSTALLATION

■ 150. The authority citation for part 182 continues to read as follows:

Authority: 46 U.S.C. 3306; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

§ 182.440 [Amended]

■ 151. Amend § 182.440 as follows:

■ a. In paragraph (a)(1), remove the text “Table 182.440(a)(1)” wherever it appears, and add, in its place, the text “Table 1 to § 182.440(a)(1)”; and

■ b. In Table 182.440(a)(1), remove the text “Table 182.440(a)(1)” and add, in its place, the text “Table 1 to § 182.440(a)(1)”.

PART 189—INSPECTION AND CERTIFICATION

■ 152. The authority citation for part 189 continues to read as follows:

Authority: 33 U.S.C. 1321(j); 46 U.S.C. 2113, 3306, 3307; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; Department of Homeland Security Delegation No. 0170.1.

■ 153. Revise § 189.55–15(a)(2) to read as follows:

§ 189.55–15 Procedure for submittal of plans.

(a) * * *

(2) The plans may be submitted by visitors directly to the Commanding Officer, Marine Safety Center, U.S. Coast Guard, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593, or transmitted by mail to: Commanding Officer (MSC), Attn: Marine Safety Center, U.S. Coast Guard Stop 7430, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593–7430, in a written or electronic format. Information for submitting the VSP electronically can be found at <http://www.uscg.mil/HQ/MSC>. In this case, the plans will be returned directly to the submitter, with a copy of the action being forwarded to the interested Officer in Charge, Marine Inspection.

* * * * *

Katia Kroutil,

Chief, Office of Regulations and Administrative Law, U.S. Coast Guard.

[FR Doc. 2017–14617 Filed 7–27–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 100**

[Docket No. USCG–2017–0508]

Special Local Regulations; EQT Pittsburgh Three Rivers Regatta, Pittsburgh, PA

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a special local regulation for navigable waters of the Allegheny, Ohio, and Monongahela Rivers during the EQT Pittsburgh Three Rivers Regatta. This regulation is needed to provide for the safety of life during the marine event. During the enforcement period, entry into this regulated area is prohibited to all vessels not registered with the sponsor as participants or official patrol vessels, unless specifically authorized by the Captain of the Port Marine Safety Unit Pittsburgh (COTP) or a designated representative.

DATES: The regulations in 33 CFR 100.801, Table 1, Sector Ohio Valley, line 20, will be enforced each day from August 4, 2017 through August 6, 2017.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email MST1 Jennifer Haggins, Marine Safety Unit

Pittsburgh, U.S. Coast Guard; telephone 412-221-0807, email Jennifer.L.Haggins@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce a special local regulation for the annual EQT Pittsburgh Three Rivers Regatta listed in 33 CFR 100.801, Table 1, line 20, from August 4, 2017 through August 6, 2017. Entry into the regulated area is prohibited unless authorized by the Captain of the Port Marine Safety Unit Pittsburgh (COTP) or a designated representative. Persons or vessels desiring to enter into or pass through the area must request permission from the COTP or a designated representative. If permission is granted, all persons and vessels shall comply with the instructions of the COTP or designated representative.

This notice of enforcement is issued under authority of 33 CFR 100.801 and 5 U.S.C. 552(a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via Local Notice to Mariners and updates via Marine Information Broadcasts.

Dated: July 20, 2017.

L. McClain, Jr.,

Commander, U.S. Coast Guard, Captain of the Port Marine Safety Unit Pittsburgh.

[FR Doc. 2017-15924 Filed 7-27-17; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG-2017-0592]

Special Local Regulations; Wheeling Vintage Raceboat Regatta, Ohio River Miles 90.4-91.5

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a special local regulation during the Wheeling Vintage Raceboat Regatta on the Ohio River miles 90.4 to 91.5, for all navigable waters of the river. This regulation is needed to protect vessels transiting the area and event spectators from the hazards associated with the Wheeling Vintage Raceboat Regatta. During the enforcement period, entry into, transiting, or anchoring in the regulated area is prohibited to all vessels not registered with the sponsor as participants or official patrol vessels,

unless specifically authorized by the Captain of the Port Marine Safety Unit Pittsburgh (COTP) or a designated representative.

DATES: The regulations in 33 CFR 100.801, Table 1 Sector Ohio Valley, No. 28 will be enforced from 9 a.m. until 6 p.m., each day from September 2, 2017 through September 3, 2017.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email MST1 Jennifer Haggins, Marine Safety Unit Pittsburgh, U.S. Coast Guard; telephone 412-221-0807, email Jennifer.L.Haggins@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce special local regulations for the annual Wheeling Vintage Raceboat Regatta in 33 CFR 100.801, Table 1 Sector Ohio Valley, No. 28 from 9 a.m. until 6 p.m. each day from September 2, 2017 through September 3, 2017. Entry into the regulated area is prohibited unless authorized by the Captain of the Port Marine Safety Unit Pittsburgh (COTP) or a designated representative. Persons or vessels desiring to enter into or pass through the area must request permission from the COTP or a designated representative. If permission is granted, all persons and vessels shall comply with the instructions of the COTP or designated representative.

This notice of enforcement is issued under authority of 33 CFR 100.801 and 5 U.S.C. 552 (a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via Local Notice to Mariners and updates via Marine Information Broadcasts.

Dated: July 20, 2017.

L. McClain, Jr.,

Commander, U.S. Coast Guard, Captain of the Port Marine Safety Unit Pittsburgh.

[FR Doc. 2017-15923 Filed 7-27-17; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2017-0485]

Drawbridge Operation Regulation; Lewis Creek Channel, Chincoteague, VA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the SR 175 Bridge, mile 0.0 across the Lewis Creek Channel, at Chincoteague, VA. This deviation allows the bridge to remain in the closed-to-navigation position to facilitate bridge maintenance work.

DATES: The deviation is effective from Noon, on September 20, 2017, through 6 p.m. on September 21, 2017.

ADDRESSES: The docket for this deviation, [USCG-2017-0485] is available at <http://www.regulations.gov>. Type the docket number in the "SEARCH" box and click "SEARCH". Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Martin Bridges, Bridge Administration Branch Fifth District, Coast Guard, telephone 757-398-6422, email Martin.A.Bridges@uscg.mil.

SUPPLEMENTARY INFORMATION: The Virginia Department of Transportation, who owns and operates the SR 175 Bridge, mile 0.0 across the Lewis Creek Channel, at Chincoteague, VA, has requested a temporary deviation from the current operating regulation set out in 33 CFR 117.5, to perform maintenance on the movable span.

Under this temporary deviation, the bridge will remain in the closed-to-navigation position from Noon on September 20, 2017, through 6 p.m. on September 21, 2017. The bridge is a bascule span drawbridge with a vertical clearance of 15 feet above mean high water in the closed-to-navigation position and unlimited vertical clearance in the open position.

The Lewis Creek Channel is used by recreational vessels. The Coast Guard has carefully considered the nature and volume of vessel traffic on the waterway in publishing this temporary deviation.

Vessels able to pass through the bridge in the closed-to-navigation position may do so at anytime. The bridge will not be able to open for emergencies and there is no immediate alternate route for vessels unable to pass through the bridge in the closed position while maintenance is being performed. The Coast Guard will also inform the users of the waterway through our Local Notice and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessel operators can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the

end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: July 24, 2017.

Hal R. Pitts,

Bridge Program Manager, Fifth Coast Guard District.

[FR Doc. 2017-15920 Filed 7-27-17; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2017-0733]

RIN 1625-AA00

Safety Zone; Commencement Bay, Tacoma, WA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for certain navigable waters on the south west side of Commencement Bay. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by vessels navigating at high speed with skiers in tow. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Puget Sound.

DATES: This rule is effective from 9 a.m. until 2 p.m. on July 28, 2017.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG-2017-0733 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 Petty Officer Zachary Spence, Sector Puget Sound, Waterways Management Division, Coast Guard; telephone (206) 217-6051, email SectorPugetSound@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
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 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)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because publishing an NPRM would be impracticable as delayed promulgation may result in injury or damage to persons and vessels in the vicinity of Commencement Bay, WA prior to the conclusion of a notice and comment period.

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 would be impracticable because the safety hazards associated with vessels operating at high rates of speed with skiers in tow will occur on July 28, 2017, and this rule must be effective to protect against those hazards.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The Captain of the Port Puget Sound (COTP) has determined that potential hazards associated with vessels operating at high speed with skiers in tow starting July 28, 2017 will be a safety concern for anyone within the practice area. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while the practice runs are ongoing.

On July 21, 2017 Sector Puget Sound received notice of the request for a safety zone from the event organizer.

IV. Discussion of the Rule

This rule establishes a safety zone from 9 a.m. until 2 p.m. on July 28, 2017. The safety zone will cover certain navigable waters within Commencement Bay where the practice runs are taking place. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters while the practice runs are being conducted. No vessel or person will be

permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 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 action determination is based on the limited nature of the size, location, duration, and time-of-day of the safety zone. Vessel traffic will be able to safely transit around this safety zone which would impact a small area of Commencement Bay for less than 5 hours during the afternoon. Moreover the Coast Guard would issue a Broadcast Notice to Mariner via VHF-FM marine channel 16 about the zone, and the rule would allow 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 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 (Public Law 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 an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting less than 5 hours that will prohibit entry within certain waters of Commencement Bay. It is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

- 2. Add § 165.T13–0733 to read as follows:

§ 165.T13–0733 Safety Zone; Commencement Bay, Tacoma, WA.

(a) *Location.* The following area is a safety zone: All waters of Commencement Bay encompassed within an imaginary line connecting the following coordinates: starting at point 1 in position 47°18'9.6" N., 122°30'23.6" W.; thence northeast to Point 2 in position 47°18'15.2" N., 122°30'14.4" W.; thence east to Point 3 in position 47°18'32" N., 122°28'41.3" W.; thence south to Point 4 in position 47°17'32" N., 122°28'22.4" W.; thence southwest to Point 5 in position 47°17'5.5" N., 122°29'6.4" W.; thence northwest back to origin.

(b) *Definitions.* For the purpose of this section the following definitions apply:

Designated representative means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Puget Sound (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by contacting the Joint Harbor Operations Center at 206–217–6001, or the on-scene patrol craft, if any via VHF–FM channel 16. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This section will be enforced from 9 a.m. until 2 p.m. on July 28, 2017.

Dated: July 24, 2017.

Linda A. Sturgis,

Captain, U.S. Coast Guard, Captain of the Port Puget Sound.

[FR Doc. 2017–15958 Filed 7–27–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 165**

[Docket No. USCG–2017–0346]

Safety Zone; Wheeling Heritage Port Sternwheel Festival Foundation/ Wheeling Heritage Port Sternwheel Festival, Ohio River, Miles 90.2 to 90.7, Wheeling, WV**AGENCY:** Coast Guard, DHS.**ACTION:** Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the subject safety zone for the Wheeling Heritage Port Sternwheel Festival Foundation/Wheeling Heritage Port Sternwheel Festival Fireworks on the Ohio River on September 16, 2017 to protect vessels transiting the area and event spectators from the hazards associated with the barge-based fireworks display. During the enforcement period, entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Marine Safety Unit Pittsburgh (COTP) or a designated representative.

DATES: The regulations in 33 CFR 165.801, Table 1 Sector Ohio Valley, No. 58 will be enforced from 10 p.m. through 11:15 p.m., on September 16, 2017.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email MST1 Jennifer Haggins, Marine Safety Unit Pittsburgh, U.S. Coast Guard; telephone 412–221–0807, email Jennifer.L.Haggins@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the Safety Zone for the annual Wheeling Heritage Port Sternwheel Festival Foundation/ Wheeling Heritage Port Sternwheel Festival Fireworks listed in 33 CFR 165.801, Table 1 Sector Ohio Valley from 10 p.m. to 11:15 p.m. on September 16, 2017. Entry into the safety zone is prohibited unless authorized by the Captain of the Port Marine Safety Unit Pittsburgh (COTP) or a designated representative. Persons or vessels desiring to enter into or passage through the safety zone must request permission from the COTP or a designated representative. If permission is granted, all persons and vessels shall comply with the instructions of the COTP or designated representative.

This notice of enforcement is issued under authority of 33 CFR 165.801 and

5 U.S.C. 552(a). In addition to this notice of enforcement in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of these enforcement periods via Local Notice to Mariners and updates via Marine Information Broadcasts.

Dated: July 20, 2017.

L. McClain, Jr.,

Commander, U.S. Coast Guard, Captain of the Port Marine Safety Unit Pittsburgh.

[FR Doc. 2017–15922 Filed 7–27–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 165**

[Docket Number USCG–2017–0534]

RIN 1625–AA00

Safety Zone; Whiskey Island Paddlefest, Lake Erie, Cleveland, OH**AGENCY:** Coast Guard, DHS.**ACTION:** Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on Lake Erie, Cleveland Harbor, Cleveland, OH. This safety zone is intended to restrict vessels from a portion of Lake Erie during the Whiskey Island Paddlefest on August 19, 2017. This temporary safety zone is necessary to protect mariners and race participants from the navigational hazards associated with a paddle craft race. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sector Buffalo.

DATES: This rule is effective from 6:45 a.m. through 11 a.m. on August 19, 2017.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG–2017–0534 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 LT Ryan Junod, Chief of Waterways Management, U.S. Coast Guard Marine Safety Unit Cleveland; telephone 216–937–0124, email ryan.s.junod@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations

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 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)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the event sponsor did not submit notice to the Coast Guard with sufficient time remaining before the event to publish an NPRM. Thus, delaying the effective date of this rule to wait for a comment period to run would be contrary to the public interest by inhibiting the Coast Guard’s ability to protect participants and vessels from the hazards associated with a paddle craft race.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this temporary rule effective less than 30 days after publication in the **Federal Register** because doing so would be impracticable and contrary to the public interest. Delaying the effective date would be contrary to the rule’s objectives of ensuring safety of life on the navigable waters and protection of persons and vessels near the event.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The Captain of the Port Buffalo, NY (COTP) has determined that a large scale paddle craft event on a navigable waterway will pose a significant risk to participants and the boating public. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while the Whiskey Island Paddlefest is happening.

IV. Discussion of the Rule

This rule establishes a safety zone from 6:45 a.m. through 11 a.m. on August 19, 2017. This zone will encompass all waters of Lake Erie; Cleveland Harbor, Cleveland, OH from 41°29′59.5″ N. and 081°42′59.3″ W. to 41°30′4.4″ N. and 081°42′44.5″ W. to

41°30'17.3" N. and 081°43'0.6" W. to 41°30'9.4" N. and 081°43'2.0" W. to 41°29'54.9" N. and 081°43'34.4" W. to 41°30'0.1" N. and 081°43'3.1" W. and back to 41°29'59.5" N. and 081°42'59.3" W. (NAD 83). No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port Buffalo or his designated on-scene representative. The Captain of the Port or his designated on-scene representative may be contacted via VHF Channel 16.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

Executive Order 13771 ("Reducing Regulation and Controlling Regulatory Costs"), directs agencies to reduce regulation and control regulatory costs and provides that "for every one new regulation issued, at least two prior regulations be identified for elimination, and that the cost of planned regulations be prudently managed and controlled through a budgeting process."

This rule has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget.

As this rule is not a significant regulatory action, this rule is exempt from the requirements of 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).

We conclude that this rule is not a significant regulatory action because we anticipate that it will have minimal impact on the economy, will not interfere with other agencies, will not adversely alter the budget of any grant

or loan recipients, and will not raise any novel legal or policy issues. The safety zone created by this rule will be relatively small and enforced for a relatively short time. Also, the safety zone is designed to minimize its impact on navigable waters. Furthermore, the safety zone has been designed to allow vessels to transit around it. Thus, restrictions on vessel movement within that particular area are expected to be minimal. Under certain conditions, moreover, vessels may still transit through the safety zone when permitted by the Captain of the Port.

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 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 an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting 4 hours and 15 minutes that will prohibit entry within a small area

on Lake Erie. It is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. A Record of Environmental Consideration (REC) supporting this determination is available in the docket where indicated in the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add § 165.T09–0534 to read as follows:

§ 165.T09–0534 Safety Zone; Whiskey Island Paddlefest; Lake Erie, Cleveland, OH.

(a) *Location.* This zone will encompass all waters of Lake Erie; Cleveland Harbor, Cleveland, OH from 41°29'59.5" N. and 081°42'59.3" W. to 41°30'4.4" N. and 081°42'44.5" W. to 41°30'17.3" N. and 081°43'0.6" W. to 41°30'9.4" N. and 081°43'2.0" W. to 41°29'54.9" N. and 081°43'34.4" W. to 41°30'0.1" N. and 081°43'3.1" W. and back to 41°29'59.5" N. and 081°42'59.3" W. (NAD 83).

(b) *Effective and enforcement period.* This regulation is effective and will be enforced on August 19, 2017 from 6:45 a.m. until 11 a.m.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Buffalo or his designated on-scene representative.

(2) This safety zone is closed to all vessel traffic, except as may be permitted by the Captain of the Port

Buffalo or his designated on-scene representative.

(3) The “on-scene representative” of the Captain of the Port Buffalo is any Coast Guard commissioned, warrant or petty officer who has been designated by the Captain of the Port Buffalo to act on his behalf.

(4) Vessel operators desiring to enter or operate within the safety zone shall contact the Captain of the Port Buffalo or his on-scene representative to obtain permission to do so. The Captain of the Port Buffalo or his on-scene representative may be contacted via VHF Channel 16. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the Captain of the Port Buffalo, or his on-scene representative.

Dated: July 21, 2017.

Joseph S. Dufresne,
Captain, U.S. Coast Guard, Captain of the Port Buffalo.

[FR Doc. 2017–15889 Filed 7–27–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2017–0714]

RIN 1625–AA00

Safety Zone; Ogdensburg Summer Seaway Festival; Saint Lawrence Seaway, Ogdensburg, NY

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the Saint Lawrence River, Ogdensburg, NY. This safety zone is intended to restrict vessels from portions of the Saint Lawrence River during the Ogdensburg Seaway Summer Festival fireworks display on July 28, 2017. This temporary safety zone is necessary to protect mariners and vessels from the navigational hazards associated with a fireworks display. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Buffalo.

DATES: This rule is effective from 9:45 p.m. to 10:45 p.m. on July 28, 2017.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG–2017–0714 in the “SEARCH” box and click “SEARCH.” Click on Open Docket

Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rulemaking, call or email LT Michael Collet, Chief of Waterways Management, U.S. Coast Guard Sector Buffalo; telephone 716–843–9322, email D09-SMB-SECBuffalo-WWM@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
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 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)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule. The event sponsor did not submit notice to the Coast Guard with sufficient time remaining before the event to publish an NPRM. Delaying the effective date of this rule to wait for a comment period to run would be impracticable and contrary to the public interest by inhibiting the Coast Guard’s ability to protect spectators and vessels from the hazards associated with a fireworks display.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this temporary rule effective less than 30 days after publication in the **Federal Register** because doing so would be impracticable and contrary to the public interest. Delaying the effective date would be contrary to the rule’s objectives of ensuring safety of life on the navigable waters and protection of persons and vessels in the vicinity of the fireworks display.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The Captain of the Port Buffalo (COTP) has determined that a fireworks display presents significant risks to public safety and property. Such hazards include premature and accidental

detonations, dangerous projectiles, and falling or burning debris. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while the fireworks display takes place.

IV. Discussion of the Rule

This rule establishes a safety zone on July 28, 2017 from 9:45 p.m. to 10:45 p.m. The safety zone will encompass all waters of the Saint Lawrence River; Ogdensburg, NY contained within 420-foot radius of: 44°42'04.4" N., 075°29'41.3" W. (NAD 83).

Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port Buffalo or his designated on-scene representative. The Captain of the Port or his designated on-scene representative may be contacted via VHF Channel 16.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Executive Order 13771 ("Reducing Regulation and Controlling Regulatory Costs"), directs agencies to reduce regulation and control regulatory costs and provides that "for every one new regulation issued, at least two prior regulations be identified for elimination, and that the cost of planned regulations be prudently managed and controlled through a budgeting process."

This rule has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget.

As this rule is not a significant regulatory action, this rule is exempt from the requirements of 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).

We conclude that this rule is not a significant regulatory action because we anticipate that it will have minimal impact on the economy, will not interfere with other agencies, will not adversely alter the budget of any grant or loan recipients, and will not raise any novel legal or policy issues. The safety zone created by this rule will be relatively small and enforced only during the fireworks display. Also, the safety zone is designed to minimize its impact on navigable waters. Furthermore, the safety zone has been designed to allow vessels to transit around it. Thus, restrictions on vessel movement within the particular areas are expected to be minimal. Under certain conditions, moreover, vessels may still transit through the safety zone when permitted by the Captain of the Port.

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 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 an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42

U.S.C. 4321–4370f), and have determined that it is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule establishes a temporary safety zone. It is categorically excluded under section 2.B.2, figure 2–1, paragraph 34(g) of the Instruction, which pertains to establishment of safety zones. A Record of Environmental Consideration (REC) supporting this determination is available in the docket where indicated in the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

- 2. Add § 165.T09–0714 to read as follows:

§ 165.T09–0714 Safety Zone; Ogdensburg Seaway Summer Festival, Saint Lawrence River, Ogdensburg, NY.

(a) *Location.* The safety zone will encompass all waters of the Saint Lawrence River; Ogdensburg, NY contained within a 420-foot radius of: 44°42'04.4" N., 075°29'41.3" W. (NAD 83).

(b) *Enforcement period.* This regulation will be enforced on July 28, 2017 from 9:45 p.m. until 10:45 p.m.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Buffalo or his designated on-scene representative.

(2) This safety zone is closed to all vessel traffic, except as may be

permitted by the Captain of the Port Buffalo or his designated on-scene representative.

(3) The “on-scene representative” of the Captain of the Port Buffalo is any Coast Guard commissioned, warrant or petty officer who has been designated by the Captain of the Port Buffalo to act on his behalf.

(4) Vessel operators desiring to enter or operate within the safety zone must contact the Captain of the Port Buffalo or his on-scene representative to obtain permission to do so. The Captain of the Port Buffalo or his on-scene representative may be contacted via VHF Channel 16. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the Captain of the Port Buffalo, or his on-scene representative.

Dated: July 25, 2017.

Joseph S. Dufresne,

Captain, U.S. Coast Guard, Captain of the Port Buffalo.

[FR Doc. 2017–15973 Filed 7–27–17; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2017–0365; FRL–9965–30–Region 4]

Air Plan Approval; Kentucky; Revisions to Louisville; Definitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: On August 29, 2012, the Commonwealth of Kentucky, through the Kentucky Division for Air Quality (KDAQ), submitted changes to the Kentucky State Implementation Plan (SIP) on behalf of the Louisville Metro Air Pollution Control District (District). The Environmental Protection Agency (EPA) is taking direct final action to approve a portion of the submission that modifies the District’s air quality regulations as incorporated into the SIP. Specifically, the revision pertains to definitional changes, including the modification of the definition of “volatile organic compounds” (VOCs). EPA is taking direct final action to approve this portion of the SIP revision because the Commonwealth has demonstrated that these changes are consistent with the Clean Air Act (CAA or Act). EPA will act on the other portion of KDAQ’s August 29, 2012, submittal in a separate action.

DATES: This direct final rule is effective September 26, 2017 without further notice, unless EPA receives adverse comment by August 28, 2017. If adverse comment is received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2017–0365 at <http://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT:

Nacosta C. Ward, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9140. Ms. Ward can be reached via electronic mail at ward.nacosta@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In this rulemaking, EPA is proposing to approve a portion of the changes to the Louisville Metro air quality regulations in the Kentucky SIP, submitted by the Commonwealth on August 29, 2012. The submission revises Louisville Metro Regulation 1.02—*Definitions* and Regulation 2.03—*Permit Requirements: Non-Title V Construction and Operating Permits and Demolition/Renovation Notices and Permit Requirements*. This rulemaking only pertains to Regulation 1.02, which adds, removes, and modifies several definitions and titles in the SIP,

including the modification of the definition of VOCs. EPA is not taking action on the proposed changes to Regulation 2.03 at this time.

As it relates to the modification of the definition of VOCs, SIPs contain compounds of carbon that need not be regulated to reduce ozone. *See* 42 FR 35314, July 8, 1977. Tropospheric ozone, commonly known as smog, occurs when VOCs and nitrogen oxides (NO_x) react in the atmosphere. Because of the harmful health effects of ozone, EPA limits the amount of VOCs and NO_x that can be released into the atmosphere. VOCs are those compounds of carbon (excluding carbon monoxide, carbon dioxide, carbonic acid, metallic carbides or carbonates, and ammonium carbonate) that form ozone through atmospheric photochemical reactions. Compounds of carbon (or organic compounds) have different levels of reactivity; they do not react at the same speed, or do not form ozone to the same extent.

EPA determines whether a given carbon compound has “negligible” reactivity by comparing the compound’s reactivity to the reactivity of ethane. EPA lists these compounds in its regulations at 40 CFR 51.100(s) and excludes them from the definition of VOC. The chemicals on this list are often called “negligibly reactive.” EPA may periodically revise the list of negligibly reactive compounds to add or delete compounds.

On November 29, 2004, January 18, 2007, and January 21, 2009, EPA issued final rules revising the definition of VOCs to add new negligibly reactive compounds and make nomenclature clarifications to previously-exempted compounds. The compounds that are being modified in this SIP revision are 1,1,1,2,2,3,3-heptafluoro-3-methoxypropane (n-C₃F₇OCH₃) (known as HFE-7000), methyl formate (HCOOCH₃), 1,1,1,2,2,3,3,4,4-nonafluoro-4-methoxybutane (C₄F₉OCH₃) (known as HFE-7100), and 1-ethoxy-1,1,2,2,3,3,4,4,4-nonafluorobutane (C₄F₉OC₂H₅) (known as HFE-7200).¹ The Commonwealth’s August 29, 2012, SIP revision modifies these compounds by adding the

nomenclature clarifications in its SIP-approved definition of VOCs.

The compounds that are being added to the list of negligibly reactive compounds in this SIP revision are methoxy-4-trifluoromethyl-pentane (also known as HFE-7300) or C₂F₅CF(OCH₃)CF(CF₃)₂,² dimethyl carbonate, and propylene carbonate.³ HFE-7300 has a variety of potential uses including heat transfer fluids in heat transfer processes and as a substitute for ozone depleting substances and substances with high global warming potential. Because HFEs do not contain chlorine or bromine, these compounds do not contribute to the depletion of the ozone layer and have ozone depletion potential values of zero. Dimethyl carbonate may be used as a solvent in paints and coatings. Propylene carbonate has been used in cosmetics as an adhesive component in food packaging and as a solvent for aerial pesticide application. In the past, EPA has considered three different metrics to compare the reactivity of a specific compound to that of ethane: (i) The reaction rate constant with the hydroxyl radical (known as k_{OH}), (ii) maximum incremental reactivities (MIR) expressed on a reactivity per gram (mass) basis, and (iii) MIR expressed on a reactivity per mole basis. When compared to ethane, both dimethyl carbonate and propylene carbonate were added to the list of exempt compounds and deemed negligibly reactive since they are equal to or less reactive than ethane on a mass basis. As a result of this determination, the Commonwealth is updating the Louisville Metro portion of its SIP to be consistent with Federal regulations.

II. EPA’s Analysis of Kentucky’s SIP Revision

The August 29, 2012, SIP submission revises Regulation 1.02 by adding, removing, and modifying definitions and titles within the SIP. Specifically, all instances of “Jefferson County” have been replaced with “Louisville Metro” due to the merger of the City of Louisville and Jefferson County governments. The proposed SIP submission also makes changes to the definition of “Cabinet” to reflect the name change of the Cabinet of the Commonwealth of Kentucky. The remainder of the changes to Regulation

1.02 consist of updates to the definitions to make them consistent with definitions used by EPA, specifically the modifications and additions to exemptions from the definition of VOCs. The changes also include renumbering the entire regulation as a result of the removal of the terms “cancer,” “carcinogen,” “chronic noncancer effect,” “toxic air contaminant,” and “toxic air pollutant.” The terms “cancer,” “carcinogen,” “chronic noncancer effect,” “toxic air contaminant,” and “toxic air pollutant” while deleted from Regulation 1.02, have been moved to Regulation 5.00. In this action, EPA is approving the renumbering of this regulation because these terms have been moved. Modifications are also being made to the term “acute noncancer effect.” EPA is not approving changes to the term “acute noncancer effect” because EPA only approves terms that relate to the attainment and maintenance of the national ambient air quality standards.

EPA believes that these proposed changes to the regulatory portion of the SIP are consistent with section 110 of the CAA and meet the regulatory requirements pertaining to SIPs. Pursuant to CAA section 110(l), the Administrator shall not approve a revision of a plan if the revision would interfere with any applicable requirement concerning attainment and reasonable further progress (as defined in CAA section 171), or any other applicable requirement of the Act. With respect to the District’s addition of exemptions from the definition of VOCs, the change is approvable under section 110(l) because it reflects changes to Federal regulations based on findings that the exempted compounds are negligibly reactive. With respect to the District’s renumbering and wording changes, the changes are approvable under section 110(l) because they are ministerial in nature.

III. Incorporation by Reference

In this rule, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of Louisville Metro Regulation 1.02—*Definitions* (except for the change to the term “acute noncancer effect”), effective June 15, 2011, changes to definitions. Therefore, these materials have been approved by EPA for inclusion in the State implementation plan, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking

¹ In EPA’s November 29, 2004, final rulemaking, the Agency adds 1,1,1,2,2,3,3-heptafluoro-3-methoxypropane (n-C₃F₇OCH₃) (known as HFE-7000) and methyl formate (HCOOCH₃) to the list of excluded compounds from the definition of VOCs. In the same rulemaking, EPA makes nomenclature clarifications to the previously-exempted compounds 1,1,1,2,2,3,3,4,4-nonafluoro-4-methoxybutane (C₄F₉OCH₃) (known as HFE-7100) and 1-ethoxy-1,1,2,2,3,3,4,4,4-nonafluorobutane (C₄F₉OC₂H₅) (known as HFE-7200). *See* 69 FR 69290. The Commonwealth’s SIP currently contains these compounds.

² In EPA’s January 18, 2007, final rulemaking, the Agency adds methoxy-4-trifluoromethyl-pentane (also known as HFE-7300) or C₂F₅CF(OCH₃)CF(CF₃)₂ to the list of excluded compounds from the definition of VOCs. *See* 72 FR 2193.

³ In EPA’s January 21, 2009, final rulemaking, the Agency adds dimethyl carbonate and propylene carbonate to the list of excluded compounds from the definition of VOCs. *See* 74 FR 3441.

of EPA's approval, and will be incorporated by reference by the Director of the Federal Register in the next update to the SIP compilation.⁴ EPA has made, and will continue to make, these materials generally available through www.regulations.gov and/or at the EPA Region 4 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information)

IV. Final Action

EPA is taking direct final action to approve portions of Kentucky's August 29, 2012 submission submitted by the Commonwealth of Kentucky through KDAQ on behalf of the District. The submission revises Louisville Metro Regulation 1.02—*Definitions*, except for the changes to the definition “Acute noncancer effect.”

EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. However, in the proposed rules section of this **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision should adverse comments be filed. This rule will be effective September 26, 2017 without further notice unless the Agency receives adverse comments by August 28, 2017.

If EPA receives such comments, then EPA will publish a document withdrawing the final rule and informing the public that the rule will not take effect. All adverse comments received will then be addressed in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period. Parties interested in commenting should do so at this time. If no such comments are received, the public is advised that this rule will be effective on September 26, 2017 and no further action will be taken on the proposed rule.

V. Statutory and Executive Order Reviews

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

those imposed by state law. For that reason, this action:

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

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

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

report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 26, 2017. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements. See section 307(b)(2).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Sulfur dioxide, Reporting and recordkeeping requirements.

Dated: July 11, 2017.

V. Anne Heard,

Acting Regional Administrator, Region 4.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart S—Kentucky

- 2. Section 52.920(c), is amended under Table 2—EPA-Approved Jefferson County Regulations for Kentucky, Reg 1—General Provisions, by revising the entry for “1.02” to read as follows:

⁴ 62 FR 27968 (May 22, 1997).

§ 52.920 Identification of plan.

(c) * * *

* * * * *

TABLE 2—EPA-APPROVED JEFFERSON COUNTY REGULATIONS FOR KENTUCKY

Reg	Title/subject	EPA approval date	FEDERAL REGISTER notice	District effective date	Explanation
1.02	Definitions	7/28/2017	[Insert citation of publication]	6/15/2011	Changes to Definitions with the exception of the term “acute noncancer effect.”

* * * * *

[FR Doc. 2017–15740 Filed 7–27–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 52****[EPA–R03–OAR–2017–0047; FRL–9965–23–Region 3]****Approval and Promulgation of Air Quality Implementation Plans; Maryland; Requirements for Continuous Emission Monitoring****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a state implementation plan (SIP) revision submitted by the State of Maryland. This revision pertains to removing a discontinued Technical Memorandum 90–01 (TM 90–01) from Maryland’s SIP, which is now superseded by a new continuous emission monitoring (CEM) regulation. EPA is approving this revision to remove TM 90–01 from Maryland’s SIP in accordance with the requirements of the Clean Air Act (CAA).

DATES: This final rule is effective on August 28, 2017.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–R03–OAR–2017–0047. All documents in the docket are listed on the <https://www.regulations.gov> Web site. Although listed in the index, some information is not publicly available, e.g., confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are

available through <https://www.regulations.gov>, or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Gavin Huang, (215) 814–2042, or by email at huang.gavin@epa.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

On July 1, 2016, MDE submitted a SIP revision to remove discontinued TM 90–01 from Maryland’s SIP because TM 90–01 had been superseded by COMAR 26.11.01.11. EPA previously approved TM 90–01 into Maryland’s SIP on February 28, 1996. *See* 61 FR 7418. MDE also submitted a revised version of COMAR 26.11.10.06 “Control of Volatile Organic Compounds from Iron and Steel Production Installations” for inclusion in the Maryland SIP which removed a reference to TM 90–01 in section C(3)(b) of COMAR 26.11.10.06 and added a reference to COMAR 26.11.01.11 in COMAR 26.11.10.06. Maryland previously used TM 90–01 to govern the CEM requirements for fuel burning equipment. The formal SIP revision (#16–08) was submitted by Maryland on July 1, 2016.

In May 2010, the State of Maryland through the Maryland Department of the Environment (MDE) discontinued the use of TM 90–01 “Continuous Emission Monitoring Policies and Procedures” and codified these requirements for CEMs in Maryland regulation COMAR 26.11.01.11 “Continuous Emission Monitoring Requirements.” MDE had been in the process of establishing unique requirements for CEMs, separate from the requirements for continuous opacity monitors (COMs), and broke out the requirements into separate COMAR regulations. On November 7, 2016 (81 FR 78048), EPA approved these separate regulations into Maryland’s SIP.

II. Summary of SIP Revision and EPA Analysis

On May 1, 2017 (82 FR 20292), EPA published a notice of proposed rulemaking (NPR) for the State of Maryland. In the NPR, EPA proposed approval of removing a discontinued TM 90–01 from Maryland’s SIP, which is now superseded by a new CEM regulation. EPA also proposed to approve for the Maryland SIP a revised version of COMAR 26.11.10.06 which removed a reference to TM 90–01 in section C(3)(b) of COMAR 26.11.10.06 and added a reference to COMAR 26.11.01.11 in COMAR 26.11.10.06 to address CEM issues. EPA’s rationale was explained in detail in the NPR and will not be restated here. No comments were received in response to EPA’s proposed approval of the July 1, 2016 Maryland SIP submittal.

III. Final Action

EPA is approving the July 1, 2016 Maryland SIP revision submittal as a revision to the Maryland SIP. The submittal sought removal of discontinued TM 90–01 from the SIP in accordance with section 110 of the CAA. The CEM requirements for quality assurance, monitoring and other technical requirements under discontinued TM 90–01 have been superseded and codified under COMAR 26.11.01.11. EPA is also approving for the Maryland SIP a revised version of COMAR 26.11.10.06 “Control of Volatile Organic Compounds from Iron and Steel Production Installations” which removed a reference to TM 90–01 in section C(3)(b) of COMAR 26.11.10.06 and added a reference to COMAR 26.11.01.11 in COMAR 26.11.10.06.

IV. Incorporation by Reference

In this rule, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation

by reference of the amended version of COMAR 26.11.10.06. Therefore, these materials have been approved by EPA for inclusion in the SIP, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference by the Director of the Federal Register in the next update to the SIP compilation.¹ EPA has made, and will continue to make, these materials generally available through <https://www.regulations.gov> and/or at the EPA Region III Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

A. General Requirements

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

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely

affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4);

- does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

B. Submission to Congress and the Comptroller General

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

This action is not a "major rule" as defined by 5 U.S.C. 804(2).

C. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 26, 2017. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action.

This action to remove discontinued TM 90-01 from Maryland's SIP and include revised COMAR 26.11.10.06 in the SIP may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Volatile organic compounds.

Dated: July 11, 2017.

Cecil Rodrigues,

Acting Regional Administrator, Region III.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart V—Maryland

- 2. Amend § 52.1070:
 - a. In the table in paragraph (c) by revising the entry for "COMAR 26.11.10.06"; and
 - b. In the table in paragraph (e) by removing the entry for "TM#90-01—'Continuous Emission Monitoring Policies and Procedures'—October 1990".

The revised text reads as follows:

§ 52.1070 Identification of plan.

* * * * *

(c) * * *

¹ 62 FR 27968 (May 22, 1997).

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

Code of Maryland Administrative Regulations (COMAR) citation	Title/subject	State effective date	EPA approval date	Additional explanation/citation at 40 CFR 52.1100
*	*	*	*	*
26.11.10 Control of Iron and Steel Production Installations				
26.11.10.06	Control of Volatile Organic Compounds from Iron and Steel Production Installations.	05/09/2016	7/28/2017 [Insert Federal Register citation].	Removed reference to TM 90-01 from C(3)(b) and added reference to COMAR 26.11.01.11.
*	*	*	*	*

* * * * *

[FR Doc. 2017-15733 Filed 7-27-17; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R04-OAR-2017-0021; FRL-9965-25-Region 4]

Air Plan Approval; Georgia; Miscellaneous Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking direct final action to approve portions of State Implementation Plan (SIP) revisions submitted by the State of Georgia, through the Georgia Department of Natural Resources' Environmental Protection Division (GA EPD), on November 29, 2010, and July 25, 2014. These changes correct a numbering error, clarify rule applicability and remove obsolete tables and references in multiple rules. EPA is approving portions of these SIP revisions because the State has demonstrated that they are consistent with the Clean Air Act (CAA or Act).

DATES: This direct final rule is effective September 26, 2017 without further notice, unless EPA receives adverse comment by August 28, 2017. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R04-OAR-2017-0021 at <http://www.regulations.gov>. Follow the online

instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT:

Richard Wong, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303-8960. The telephone number is (404) 562-8726. Mr. Wong can also be reached via electronic mail at wong.richard@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On November 29, 2010, and July 25, 2014, GA EPD submitted revisions to EPA for review and approval into the Georgia SIP that contain changes to a number of Georgia's air quality rules in Rule 391-3-1. The changes that EPA is approving into the SIP modify Rule 391-

3-1-.01, "Definitions," and Rule 391-3-1-.02, "Provisions." The changes requested by Georgia in these proposed SIP revisions are discussed below.

The November 29, 2010, submittal includes a change to Rule 391-3-1-.01(nnnn), "Procedures for Testing and Monitoring Sources of Air Pollutants." EPA approved this change on January 5, 2017 (82 FR 1206). EPA is not acting on changes to Rule 391-3-1-.02(2)(sss), "Multipollutant Control for Electric Utility Steam Generating Units" and Rule 391-3-1-.14—"General Conformity" included in the November 29, 2010, submittal because the rules are not part of the SIP and the State's prior request to incorporate the rule into the SIP was withdrawn from EPA consideration by the State in a letter dated December 1, 2016.¹

The July 25, 2014, submittal includes several changes that are not part of this action. Rule 391-3-1-.01(III), "Volatile organic compound," was approved on October 5, 2016, (81 FR 68936) and Rule 391-3-1-.01(nnnn), "Procedures for Testing and Monitoring Sources of Air Pollutants," was approved on January 5, 2017, (82 FR 1206). With respect to GA EPD's submission related to Rule 391-3-1-.02(4), "Ambient Air Standards," and Rule 391-3-1-.03(8), "Permit Requirements," EPA will act on these changes in a separate action.

II. Analysis of State's Submittal

A. November 29, 2010 Submittal

Georgia's November 29, 2010, submittal makes only one administrative edit to Rule 391-3-1-.02(2)(ss), "Gasoline Transport Vehicles and Vapor Collection Systems." Specifically, the submittal fixes a numbering error at Rule 391-3-

¹ The December 1, 2016 letter is included in the docket for this action.

1.02(2)(ss)(5) by revising the citation for a provision defining the term “Vapor Control System” from “iv” to “vi.” EPA is approving this administrative change to Rule 391-3-1-.02(2)(ss) into the SIP. This change became state effective on October 6, 2010.

B. July 25, 2014 Submittal

Georgia's July 25, 2014, submission makes multiple changes to Rule 391-3-1-.02.

GA EPD revises two sections in Rule 391-3-1-.02(2)(a), “General Provisions.” The first change adds a subparagraph at Rule 391-3-1-.02(2)(a)6.(i)(VI), which clarifies applicability requirements for certain volatile organic compound (VOC) emission standards. This change clarifies that, when calculating emissions for purposes of an applicability determination for each standard, the source should only include emissions from units belonging to the source category to which the standard would apply.

The second change removes a paragraph at Rule 391-3-1.02(2)(a)9., titled *Kraft Pulp Mill Total Reduced Sulfur (TRS) Compliance Schedules*. Kraft Pulp Mill sources were required to comply with the TRS Compliance Schedule no later than 43 months after the September 1, 1988, notification date. New sources after April 1, 1992, have to be in compliance upon start-up. The July 25, 2014, SIP submittal deletes paragraph 9 because sources have met the TRS compliance schedule, so the provision is obsolete. Additionally, Georgia makes an administrative change to Rule 391-3-1-.02 (2)(gg), “Kraft Pulp Mills,” by removing reference to the approval of the TRS Compliance Schedule in subparagraph 2(i)(V).

Rule 391-3-1-.02(2)(e), “Particulate Emission from Manufacturing Processes,” establishes allowable particulate matter emission limits for sources that are not subject to another rule or permit condition. The rule currently provides equations to calculate allowable emission rates based on process input weight rate for new and existing equipment. In addition, two tables, Ia and Ib, also provide the allowable emissions rates. Georgia is removing these two tables since the equations in the rule serve the same purpose, and as such this change is administrative in nature.

Rule 391-3-1-.02(2)(l), “Conical Burners.” This rule was first incorporated in the SIP to address the use of conical burners for wood waste burning. These burners gradually went out of service and are no longer in operation in Georgia. The July 25, 2014, SIP submittal removes the regulation for

conical burners as it is no longer applicable and is obsolete. Moreover, if a source were to begin operating in Georgia in the future, it would be subject to new source review, as well as the new source performance standards and emission guidelines for commercial and industrial solid waste incineration units in 40 Code of Federal Regulations (CFR) Part 60 Subparts CCCC and DDDD, thus ensuring that the source would not interfere with any applicable requirement under the CAA.

Rule 391-3-1-.02(2)(o), “Cupola Furnaces for Metallurgical Melting.” This rule was first incorporated in the SIP to address particulate emissions from foundries. These sources are no longer operating in Georgia. This change removes the regulation for cupola furnaces for metallurgical melting as it is no longer applicable and is obsolete. Moreover, if a source were to begin operating in the future, it would be subject to new source review, as well as 40 CFR part 63 Subpart EEEEE or ZZZZZ, thus ensuring that the source would not interfere with any applicable requirement under the CAA.

Rule 391-3-1-.02(2)(p), “Particulate Emissions from Kaolin and Fuller's Earth Processes.” This rule was first incorporated in the SIP to establish allowable particulate emission limits from clay processing operations. The rule currently provides equations to calculate allowable emission rates based on process input weight rate for new and existing equipment. In addition, two tables, IIa and IIb, also provide the allowable emissions rates. Georgia is removing these two tables since the equations in the rule serve the same purpose, and as such this change is administrative in nature.

Rule 391-3-1-.02(2)(q), “Particulate Emissions from Cotton Gins.” This rule was first incorporated in the SIP to address particulate emissions from cotton ginning operations. The rule currently provides an equation to calculate allowable emission rates based on number of standard bales per hour. In addition, table IIIa also provides the allowable emissions rates. Georgia is removing this table since the equation in the rule serves the same purpose, and as such this change is administrative in nature.

Rule 391-3-1-.02(6)(a), “Specific Monitoring and Reporting Requirements for Particular Sources.” This rule was first incorporated in the SIP on September 18, 1979 (44 FR 54047), to address sources subject to any of the Standards of Performance for New Stationary Sources of or pursuant to 42 U.S.C. 7411, as amended, or National Emission Standards for Hazardous Air

Pollutants of or pursuant to 42 U.S.C. 7412. Sources subject to the rule were required to install monitoring equipment and begin monitoring within 18 months of the 1979 rulemaking. After the implementation period, new sources must be in compliance with monitoring requirements upon startup. Georgia is removing subparagraph 391-3-1-.02(6)(a)(2)(x), as the implementation period has passed and is now obsolete.

EPA is approving the aforementioned changes from the July 25, 2014, submittal into the SIP because the rules are consistent with CAA section 110. These changes became state effective on August 1, 2013.

III. Incorporation by Reference

In this rule, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of Georgia Rule 391-3-1-.02(2)(ss), “Gasoline Transport Vehicles and Vapor Collection Systems,” effective October 6, 2010, and Rule 391-3-1-.02(2)(a), “General Provisions,” Rule 391-3-1-.02(2)(e), “Particulate Emission from Cotton Gins,” Rule 391-3-1-.02(2)(p), “Particulate Emissions from Kaolin and Fuller's Earth Processes,” Rule 391-3-1-.02(2)(q), “Particulate Emissions from Cotton Gins,” Rule 391-3-1-.02 (2)(gg), “Kraft Pulp Mills,” and Rule 391-3-1-.02(6) “Specific Monitoring,” effective August 1, 2013. Therefore, these materials have been approved by EPA for inclusion in the SIP, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference by the Director of the Federal Register in the next update to the SIP compilation.² EPA has made, and will continue to make, these materials generally available through www.regulations.gov and/or at the EPA Region 4 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

IV. Final Action

EPA is approving the aforementioned changes to the SIP because they are consistent with the CFR and the CAA. EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. However, in the proposed

² 62 FR 27968 (May 22, 1997).

rules section of this **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision should adverse comments be filed. This rule will be effective September 26, 2017 without further notice unless the Agency receives adverse comments by August 28, 2017.

If EPA receives such comments, then EPA will publish a document withdrawing the final rule and informing the public that the rule will not take effect. All public comments received will then be addressed in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period. Parties interested in commenting should do so at this time. If no such comments are received, the public is advised that this rule will be effective on September 26, 2017 and no further action will be taken on the proposed rule. Please note that if we receive adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subject of an adverse comment.

V. Statutory and Executive Order Reviews

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

- Are not significant regulatory actions subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- do not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- are certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);

- do not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4);

- do not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

- are not economically significant regulatory actions based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

- are not significant regulatory actions subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

- are not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and

- do not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States

Court of Appeals for the appropriate circuit by September 26, 2017. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements. *See* section 307(b)(2).

List of Subjects in 40 CFR Part 52

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

Dated: July 12, 2017.

V. Anne Heard,

Acting Regional Administrator, Region 4.

40 CFR part 52 is amended as follows:

PART 52—[APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS]

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

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

Subpart L—Georgia

■ 2. Section 52.570(c) is amended by:

■ (A) Removing the entries for "391-3-1-.02(2)(l)," and "391-3-1-.02(2)(o)."

■ (B) Revising the entries for "391-3-1-.02(2)(a)," "391-3-1-.02(2)(e)," "391-3-1-.02(2)(p)," "391-3-1-.02(2)(q)," "391-3-1-.02(2)(gg)," "391-3-1-.02(2)(ss)," and "391-3-1-.02(6)" to read as follows:

§ 52.570 Identification of plan.

* * * * *

(c) * * *

EPA APPROVED GEORGIA REGULATIONS

State citation	Title/subject	State effective date	EPA approval date	Explanation
391-3-1-.02(2)(a)	General Provisions	8/1/2013	7/28/2017, [Insert citation of publication].	Except for paragraph 391-3-1-.02(2)(a)1 (as approved on 3/16/06).
391-3-1-.02(2)(e)	Particulate Emission from Manufacturing Processes.	8/1/2013	7/28/2017, [Insert citation of publication].	
391-3-1-.02(2)(p)	Particulate Emissions from Kaolin and Fuller's Earth Processes	8/1/2013	7/28/2017, [Insert citation of publication].	
391-3-1-.02(2)(q)	Particulate Emissions from Cotton Gins.	8/1/2013	7/28/2017, [Insert citation of publication].	
391-3-1-.02(2)(gg)	Kraft Pulp Mills	8/1/2013	7/28/2017, [Insert citation of publication].	
391-3-1-.02(2)(ss)	Gasoline Transport Systems and Vapor Collection Systems.	10/6/2010	7/28/2017, [Insert citation of publication].	
391-3-1-.02(6)	Source Monitoring	8/1/2013	7/28/2017, [Insert citation of publication].	

* * * * *

[FR Doc. 2017-15737 Filed 7-27-17; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 180****[EPA-HQ-OPP-2016-0064; FRL-9962-96]****Fenamidone; Pesticide Tolerances****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: This regulation establishes tolerances for residues of fenamidone in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 28, 2017. Objections and requests for hearings must be received on or before September 26, 2017, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2016-0064, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDfRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:**I. General Information****A. Does this action apply to me?**

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2016-0064 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before September 26, 2017. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2016-0064, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- **Mail:** OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001.

- **Hand Delivery:** To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of May 19, 2016 (81 FR 31581) (FRL-9946-02), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 5E8434) by IR-4, Rutgers University, 500 College Rd. East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR

180.579 be amended by establishing tolerances for residues of fenamidone (4H-imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino)-, (S)-) in or on the following raw agricultural commodities: Basil, fresh leaves at 30 parts per million (ppm); and basil, dried leaves at 200 ppm. Additionally, tolerances were proposed for the crops in the proposed crop subgroup 4-15A, leafy greens subgroup at 60.0 ppm, including amaranth, Chinese; amaranth, leafy; aster, Indian; blackjack; cat's whiskers; chervil, fresh leaves; cham-chwi; cham-na-mul; chipilin; chrysanthemum, garland; cilantro, fresh leaves; corn salad; cosmos; dandelion; dang-gwi; dillweed; dock; dol-nam-mul; ebolo; endive; escarole; fameflower; feather cockscomb; good king henry; huauzontle; jute, leaves; lettuce, bitter; lettuce, head; lettuce, leaf; orach; parsley, fresh leaves; plantain, buckhorn; primrose, English; purslane, garden; purslane, winter; radicchio; spinach; spinach, malabar; spinach, New Zealand; spinach, tanier; swiss chard; and violet, Chinese; the crops in the proposed crop subgroup 4-15B, *Brassica* leafy greens subgroup at 55 ppm, including arugula; broccoli raab; broccoli, Chinese; cabbage, Abyssinian; cabbage, seakale; Chinese cabbage, bok choy; collards; cress, garden; cress, upland; hanover salad; kale; maca; mizuna; mustard greens; radish, leaves; rape greens; rocket, wild; shepherd's purse; turnip greens; and watercress; the crops in the proposed crop subgroup 22B, leaf petiole vegetable subgroup at 60 ppm, including cardoon; celery; celery, Chinese; fuki; rhubarb; udo; and zuiki; the crops in the proposed crop group 5-15 (*Brassica* head and stem vegetable) at 5.0 ppm, including broccoli; brussels sprouts; cabbage; cabbage, Chinese, napa; and cauliflower; cottonseed subgroup 20C at 0.02 ppm; kohlrabi at 5.0 ppm; celtuce at 60 ppm; and fennel, Florence, fresh leaves and stalk at 60 ppm. That petition also requested that the following existing tolerances be removed after the petitioned-for tolerances are issued since they would be superseded by the new tolerances: *Brassica*, head and stem, subgroup 5A at 5.0 ppm; *Brassica*, leafy greens, subgroup 5B at 55 ppm; cotton, undelinted seed at 0.02 ppm; cilantro, leaves at 60 ppm; and vegetable, leafy, except *Brassica*, group 4 at 60 ppm. That document referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available in the docket, <http://www.regulations.gov>. No comments were received on the notice of filing.

EPA is establishing tolerances similar to those requested by the petitioner (the leafy greens crop subgroup 4-15A; the *Brassica* leafy greens crop subgroup 4-15B; the leaf petiole vegetable crop subgroup 22B; and the *Brassica* head and stem vegetable crop group 5-15), except that due to the recent establishment of the new crop groups, the Agency is referencing the current crop groups. Additionally, in order to harmonize with Canada, the Agency is establishing a single tolerance for leafy vegetable crop group 4-16 rather than two separate tolerances for each of the crop subgroup 4-16A and 4-16B.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue"

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for fenamidone including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fenamidone follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The target organs in fenamidone are the liver in mice, rats and dogs, and the thyroid in rats. Liver effects include liver weight increases, liver enlargement, and histopathological observation. Enlarged thyroid, increased thyroid weights with an increase incidence of a slight, diffuse follicular hypertrophy and/or hyperplasia were observed in rats of both sexes in the chronic toxicity study.

In the acute neurotoxicity study in rats, clinical signs included staining of the anogenital region, mucous in the feces, hunched posture, and unsteady gait. In the subchronic neurotoxicity study in rats, marginal decreases in brain weights were observed only in high dose males. Additionally, decreased brain weight occurred in the rat reproduction study. In a developmental neurotoxicity study in Wistar rats, no neurobehavioral effects and no neuropathological changes were observed at any dose in the offspring, but decreased body weight was observed during pre- and post-weaning.

Fenamidone did not demonstrate qualitative or quantitative increased susceptibility in the rat or rabbit developmental toxicity studies or the 2-generation rat reproduction study. There were no developmental effects up to the highest dose tested and in the presence of maternal toxicity in rats and rabbits. In the reproduction study in rats, decreased absolute brain weight in F2 female pups occurred at the same dose levels as decreased absolute brain

weight in F1 parental females; there were no effects on fertility or other measured reproductive parameters. Immunosuppression was demonstrated at the highest dose tested in the immunotoxicity study; however, the existing risk assessment points of departure are lower and are protective of this potential effect.

Fenamidone is classified as “not likely to be a human carcinogen” by all relevant routes of exposure. All mutagenicity studies were negative for both the parent and plant metabolites (RPA 412636, RPA 412708, and RPA 410193), except the parent induced mutant colonies at the *tk* locus and increased chromosomal aberrations in human peripheral blood.

Specific information on the studies received and the nature of the adverse effects caused by fenamidone as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in the document titled “Fenamidone: Human Health Risk Assessment to Support the Section (3) Registration on Basil and Crop Group Expansion on *Brassica* Head and Stem Vegetables; Leafy greens; *Brassica* Leafy Greens; and Cottonseed” on page 33 in docket ID number EPA-HQ-OPP-2016-0064.

B. Toxicological Points of Departure/ Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies

toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>.

A summary of the toxicological endpoints for fenamidone used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FENAMIDONE FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (All populations)	NOAEL = 125 mg/kg/day. UF _A = 10x UF _H = 10x FQPA SF = 1x	Acute RfD = 1.25 mg/kg/day. aPAD = 1.25 mg/kg/day	Acute Neurotoxicity in Rats: LOAEL = 500 mg/kg/day based on urination, staining/soiling of the anogenital region, mucous in the feces, and unsteady gait in the females.
Chronic dietary	NOAEL = 2.83 mg/kg/day. UF _A = 10x UF _H = 10x FQPA SF = 1x	Chronic RfD = 0.0283 mg/kg/day. cPAD = 0.0283 mg/kg/day	2 Year Chronic Toxicity/Carcinogenicity in Rats: LOAEL = 7.07/9.24 mg/kg/day (M/F) based on increase in severity of diffuse thyroid C-cell hyperplasia in both sexes.
Cancer (Oral, dermal, inhalation)	Fenamidone is classified as “not likely to be a human carcinogen” by all relevant routes of exposure.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary

exposure to fenamidone, EPA considered exposure under the petitioned-for tolerances as well as all

existing fenamidone tolerances in 40 CFR 180.579. EPA assessed dietary

exposures from fenamidone in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for fenamidone. In estimating acute dietary exposure, EPA used 2003–2008 food consumption information from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, "What We Eat in America" (NHANES/WWEIA). As to residue levels in food, EPA used field-trial residue values, assumed 100 percent crop treated (PCT) for all commodities, and incorporated Dietary Exposure Evaluation Model (DEEM)TM default processing factors and empirical factors for processed commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the 2003–2008 food consumption data from the USDA's NHANES/WWEIA. As to residue levels in food, EPA used field-trial residue values, assumed 100 PCT for all commodities, and incorporated Dietary Exposure Evaluation Model (DEEM)TM default processing factors and empirical factors for processed commodities.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that fenamidone does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue/Percent Crop Treated information.* Although the Agency assumed 100 percent crop treated for all commodities, EPA used anticipated residue information in the assessment for this fenamidone tolerance action. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for fenamidone in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fenamidone. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

Based on the Tier II Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS)—Index Reservoir model and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of fenamidone for acute exposures are estimated to be 41.7 parts per billion (ppb) for surface water and 207 ppb for ground water, and for chronic exposures are estimated to be 11.9 ppb for surface water and 207 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For both the acute and chronic dietary risk assessments, the ground water concentration value of 207 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Fenamidone is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found fenamidone to share a common mechanism of toxicity with any other substances, and fenamidone does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that fenamidone does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate

the cumulative effects of such chemicals, see EPA's Web site at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* Fenamidone did not demonstrate any qualitative or quantitative increased susceptibility in the rat and rabbit developmental toxicity studies or the 2-generation rat reproduction study. In rabbits and rats, there were no developmental effects up to the highest dose tested and in the presence of maternal toxicity. In the reproduction study in rats, decreased absolute brain weight in F2 female pups occurred at the same dose levels as decreased absolute brain weight in F1 parental females.

In the developmental neurotoxicity (DNT) study in rats, no maternal toxicity was observed at doses up to 4,700 ppm (429 mg/kg/day), although offspring systemic toxicity, manifested as decreased body weight (9–11%) and body weight gain (8–20%) during pre-weaning and decreased body weight (4–6%) during post-weaning, occurred at the highest dose tested (429 mg/kg/day). The offspring NOAEL of 1,000 ppm (92.3 mg/kg/day) indicates an increased susceptibility of offspring. Nevertheless, the concern for the increased susceptibility observed in the DNT is low because: (1) Of the lack of neurobehavioral or neuropathological changes in the offspring at any dose; and (2) the endpoints used for the various risk assessment scenarios are much more sensitive than that of the decreased bodyweight of the offspring occurring at almost half the limit-dose (429 mg/kg/day).

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF

were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for fenamidone is complete.
- ii. There was no evidence of neurotoxicity in the subchronic neurotoxicity study submitted for fenamidone. There was evidence of neurotoxicity (urination, staining/soiling of the anogenital region, mucous in the feces and unsteady gait in females) in the acute neurotoxicity study, and EPA used the NOAEL from this study to assess acute dietary exposure. There was also evidence of neurotoxicity (decreased absolute brain weights) in the 2-generation rat reproduction study; however, there was no indication of increased susceptibility of offspring with regard to these effects. Finally, there was no evidence of neurotoxicity at any dose in the submitted DNT study. Based on the results of these studies, EPA concluded that there is no need for additional UF_s to account for neurotoxicity.

- iii. No qualitative or quantitative increased susceptibility of rat or rabbit fetuses to *in utero* exposure in the developmental toxicity studies was observed. There was no qualitative or quantitative increased susceptibility in the two generation reproduction study (rat). There is low concern for increased susceptibility observed in the DNT study for the reasons noted in Unit III.D.2.

- iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and maximum or average field trial residue values. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fenamidone in drinking water. These assessments will not underestimate the exposure and risks posed by fenamidone.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary

exposure from food and water to fenamidone will occupy 4.9% of the aPAD for children 1–2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fenamidone from food and water will utilize 56% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. There are no residential uses for fenamidone.

3. *Short- and Intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Short- and intermediate-term adverse effects were identified; however, fenamidone is not registered for any use patterns that would result in either short- or intermediate-term residential exposure. Short- and intermediate-term risk is assessed based on short- and intermediate-term residential exposure plus chronic dietary exposure. Because there is no short- or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short- and intermediate-term risk), no further assessment of short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for fenamidone.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, fenamidone is not expected to pose a cancer risk to humans.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to fenamidone residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (liquid chromatographic method coupled with tandem mass spectrum detection (LC/MS/MS), Method RPA 407213) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350;

telephone number: (410) 305–2905; email address: residuemethods@epa.gov.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

There are Codex MRLs for flowerhead brassicas including broccoli, Chinese broccoli, and cauliflower at 4 ppm; cabbage at 0.9 ppm; lettuce at 20 ppm; and celery at 40 ppm which are all lower than the proposed U.S. tolerances. The U.S. tolerances cannot be harmonized (lowered) because following the label use directions could result in residues above the Codex MRLs.

C. Revisions to Petitioned-For Tolerances

The petitioner sought separate tolerances on the subgroups 4–16A at 60 ppm and 4–15B at 55 ppm. The Agency is establishing the whole group tolerance at 60 ppm for group 4–16, in order to harmonize with Canada.

V. Conclusion

Therefore, tolerances are established for residues of fenamidone in or on basil, dried leaves at 200 ppm; basil, fresh leaves at 30 ppm; celtuce at 60 ppm; cottonseed subgroup 20C at 0.02 ppm; fennel, Florence, fresh leaves and stalk at 60 ppm; kohlrabi at 5.0 ppm; leaf petiole vegetable subgroup 22B at 60 ppm; leafy vegetable group 4–16 at 60 ppm; and the vegetable, *Brassica*, head and stem, group 5–16 at 5.0 ppm.

Additionally, the following existing crop group tolerances are being removed since the commodities covered by those crop groups are covered by the newly established crop group tolerances: *Brassica*, head and stem subgroup 5A; *Brassica* leafy greens, subgroup 5B; cotton, undelinted seed; and vegetable,

leafy, except *Brassica*, group 4. The majority of the commodities in subgroups 5A and 5B and group 4 are explicitly included in the new group tolerances, but some commodity entries from the existing subgroup and group tolerances are not repeated in the new group tolerances. To clarify how those commodities remain covered, EPA provides the following explanation. First, subgroup 5A includes two commodities that are not explicitly covered by other group tolerances: “cabbage, Chinese mustard” and “cavalo broccolo”. As EPA discussed in its preamble to the proposed rule amending crop groups, 79 FR 68153 (Nov. 14, 2014), “cabbage, Chinese mustard” is not a distinct crop, just a general reference to leafy, non-heading *Brassica* greens, which are covered in group 4–16, and “cavalo broccolo” is the same species as cauliflower, which is covered in group 5–16. Second, subgroup 5B includes “mustard spinach”. In the same preamble document, EPA noted that “mustard spinach” is one of several names for mustard greens, which are covered by the new group 5–16. Third, group 4 includes “tampala amaranth”, “chrysanthemum, edible-leaved”, and “Indian spinach”. Each of these commodity entries are alternative names for other commodities still contained in the new group 4–16 and so no longer necessary: “edible-leaved chrysanthemum” is another name for “chrysanthemum garland”; the preferred name for “tampala amaranth” is “Chinese amaranth”; and the preferred name for “Indian spinach” is “Malabar spinach”. Therefore, residues on commodities listed in the existing group tolerances are still covered by the establishment of the new group tolerances.

Lastly, the existing entry for cilantro, leaves is being modified to read “Cilantro, fresh leaves” in accordance with Agency nomenclature.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66

FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller

General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 12, 2017.

Michael L. Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.579;

■ i. Add alphabetically the entries “Basil, dried leaves”; “Basil, fresh leaves”; “Celtuce”; “Cottonseed subgroup 20C”; “Fennel, Florence, fresh leaves and stalk”; “Kohlrabi”; “Leaf petiole vegetable subgroup 22B”; Leafy vegetable group 4–16”; and Vegetable, *Brassica*, head and stem, group 5–16” to the table in paragraph (a)(1):

■ ii. Remove the entries for “*Brassica*, head and stem subgroup 5A”; “*Brassica* leafy greens, subgroup 5B”; “Cotton, undelinted seed”; and “Vegetable, leafy, except *Brassica*, group 4” from the table in paragraph (a)(1).

■ iii. Remove the entry “Cilantro, leaves” and add in its place “Cilantro, fresh leaves”.

The additions and revisions read as follows:

§ 180.579 Fenamidone; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
Basil, dried leaves	200
Basil, fresh leaves	30
* * * * *	*
Celtuce	60
Cilantro, fresh leaves	60
* * * * *	*
Cottonseed subgroup 20C	0.02
Fennel, Florence, fresh leaves and stalk	60
* * * * *	*
Kohlrabi	5.0
Leaf petiole vegetable subgroup 22B	60
Leafy vegetable group 4–16	60

Commodity	Parts per million
* * * *	*
Vegetable, <i>Brassica</i> , head and stem, group 5–16	5.0
* * * *	*

[FR Doc. 2017–15743 Filed 7–27–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 180**

[EPA–HQ–OPP–2015–0825; FRL–9960–37]

Topramezone; Pesticide Tolerances**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: This regulation establishes a tolerance for residues of topramezone in or on sugarcane, cane. BASF Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 28, 2017. Objections and requests for hearings must be received on or before September 26, 2017, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2015–0825, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: RDfRNtices@epa.gov.

SUPPLEMENTARY INFORMATION:**I. General Information***A. Does this action apply to me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2015–0825 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before September 26, 2017. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2015–0825, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of June 22, 2016 (81 FR 40594) (FRL–9947–32), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 5F8421) by BASF Corporation, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.612 be amended by establishing a tolerance for residues of the herbicide topramezone, [3-(4,5-dihydro-isoxazol-3-yl)-4-methylsulfonyl-2-methylphenyl]-(5-hydroxyl-1-methyl-1H-pyrazol-4-yl)methanone, in or on sugarcane, cane at 0.01 parts per million (ppm). That document referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure

of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . .”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of, and to make a determination on aggregate exposure for topramezone including exposure resulting from the tolerance established by this action. EPA’s assessment of exposures and risks associated with topramezone follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Topramezone inhibits the enzyme 4-hydroxyphenylpyruvate dioxygenase (HPPD), which is involved in the catabolism of the amino acid tyrosine. HPPD-inhibition causes blood levels of tyrosine to rise (tyrosinemia), resulting in ocular, liver, kidney, and developmental effects in laboratory animals.

Similar to other HPPD inhibiting chemicals, the rat was the most sensitive species and males were found to be more sensitive than females (in rats and dogs). In rat subchronic and chronic oral studies, topramezone produced ocular (corneal vascularization, opacity, and keratitis) and kidney (microscopic findings and increased organ weights) effects, which are consistent with the mammalian toxicity profile for HPPD inhibitors caused by high tyrosine levels in the blood. Histopathological findings in the thyroid were frequently observed in rats and dogs following topramezone

exposure. Thyroid tumors via a non-linear mode of action involving thyroid hormone disruption were seen in the rat; however, topramezone is classified as “not likely to be carcinogenic to humans at doses that do not alter rat thyroid hormone homeostasis.” Additional histopathological findings were seen in the pancreas of rats and the urinary bladder in dogs. Body weight decrements were also noted in all species, including the mouse, which did not exhibit any other adverse effects in the database.

There was evidence of increased prenatal susceptibility following *in utero* exposure to topramezone in the developmental toxicity studies in rats and rabbits, with fetal skeletal variation and abnormalities observed in both species that were consistent with those reported in the toxicological databases for other HPPD inhibiting chemicals and typically seen in the absence of maternal toxicity or less severe maternal adverse effects. In the mouse developmental toxicity study, elevated tyrosine blood levels were noted in maternal animals; however, there were no developmental effects observed. There was evidence for increased qualitative offspring susceptibility in the rat developmental neurotoxicity study, where neurobehavioral and neuropathological changes were observed in the presence of limited maternal toxicity (corneal opacity). There was no evidence of increased pre- or postnatal susceptibility in the rat reproduction toxicity study.

While neurobehavioral and neuropathological offspring effects were observed in the developmental neurotoxicity study, which are indicators of potential neurotoxicity, no neurotoxic effects were observed in the acute neurotoxicity study up to the limit dose or the subchronic neurotoxicity study, where systemic effects were consistent with the rest of the toxicological database.

Topramezone is classified as having low acute toxicity (Toxicity Category III or IV) via the oral, dermal, and inhalation routes). It was found to be a slight eye and dermal irritant, but it was not found to be a dermal sensitizer.

Specific information on the studies received and the nature of the adverse effects caused by topramezone as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document *Topramezone: Human Health Risk Assessment for New Use on Sugarcane* in docket ID number EPA-HQ-OPP-2015-0825.

B. Toxicological Points of Departure/ Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>.

A summary of the toxicological endpoints for topramezone used for human risk assessment is shown in the Table of this unit.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR TOPRAMEZONE FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/Scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk Assessment	Study and toxicological effects
Acute dietary (Females 13–49 years old).	NOAEL = 0.5 mg/kg/day. UF _A = 10x UF _H = 10x FQPA SF = 1x	aRfD = 0.005 mg/kg/day. aPAD = 0.005 mg/kg/day.	<i>Rabbit Developmental Toxicity Study</i> Developmental LOAEL = 5 mg/kg/day based on alterations in skeletal ossification sites and increased number of pairs of ribs.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR TOPRAMEZONE FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/Scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk Assessment	Study and toxicological effects
Acute dietary (General population including infants and children, excluding females 13–49 years old).	LOAEL = 8 mg/kg/day .. UF _A = 10x UF _H = 10x FQPA SF/UF _L = 10x	aRfD = 0.08 mg/kg/day aPAD = 0.008 mg/kg/day.	<i>Rat Developmental Neurotoxicity Study</i> LOAEL = 8 mg/kg/day based on decreased maximum auditory startle reflex response, decreased brain weights, and changes in brain morphology.
Chronic dietary (All populations)	NOAEL = 0.4 mg/kg/day. UF _A = 10x UF _H = 10x FQPA SF = 1x	cRfD = 0.004 mg/kg/day cPAD = 0.004 mg/kg/day.	<i>Rat Chronic Toxicity/Carcinogenicity Study</i> LOAEL = 3.6 mg/kg/day based on increased incidences of corneal opacity, decreased body weight and body-weight gains in males and histopathological evaluations in the eyes, thyroid, and pancreas of both sexes.
Incidental oral short-term (1 to 30 days) and intermediate (1–6 months) term.	NOAEL = 0.4 mg/kg/day. UF _A = 10x UF _H = 10x FQPA SF = 1x	LOC for MOE = <100 ...	<i>Rat Two-Generation Reproduction Study</i> Parental/Offspring LOAEL = 4.2 mg/kg/day based on decreased body weight, increased thyroid and kidney weights, and microscopic findings in eyes, kidney, and thyroid of both sexes (parental); and decreases in body weights in the F ₂ generation and increased time to preputial separation in the F ₁ male (offspring).
Dermal short-term (1 to 30 days) and intermediate (1–6 months) term.	NOAEL = 0.4 mg/kg/day (dermal absorption rate = 2.6%). UF _A = 10x UF _H = 10x FQPA SF = 1x	LOC for MOE = <100 ...	<i>Rat Two-Generation Reproduction Study in Rats</i> Parental/Offspring LOAEL = 4.2 mg/kg/day based on decreased body weight, increased thyroid and kidney weights, and microscopic findings in eyes, kidney, and thyroid of both sexes (parental); and decreases in body weights in the F ₂ generation and increased time to preputial separation in the F ₁ male (offspring).
Inhalation short-term (1 to 30 days) and intermediate (1–6 month) term.	NOAEL = 0.4 mg/kg/day (inhalation assumed equivalent to oral). UF _A = 10x UF _H = 10x FQPA SF = 1x	LOC for MOE = <100 ...	<i>Rat Two-Generation Reproduction Study in Rats</i> Parental/Offspring LOAEL = 4.2 mg/kg/day based on decreased body weight, increased thyroid and kidney weights, and microscopic findings in eyes, kidney, and thyroid of both sexes (parental); and decreases in body weights in the F ₂ generation and increased time to preputial separation in the F ₁ male (offspring).
Cancer (Oral, dermal, inhalation)	In accordance with the 2005 EPA Guidelines for Carcinogen Risk assessment, topramezone was classified as “not likely to be carcinogenic to humans at doses that do not alter rat thyroid hormone homeostasis.” EPA has determined that the thyroid tumors arise through a non-linear mode of action and the cRfD of 0.004 mg/kg/day, which is derived from the NOAEL of 0.4 mg/kg/day from the rat chronic/carcinogenicity study, is not expected to alter thyroid hormone homeostasis nor result in thyroid tumor formation.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose (a = acute, c = chronic). UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to topramezone, EPA considered exposure under the petitioned-for tolerance as well as all existing topramezone tolerances in 40 CFR 180.612. EPA assessed dietary exposure from topramezone in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one-day or single exposure. Such effects were identified for topramezone. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA used tolerance levels and 100 percent crop treated (PCT) for the acute dietary exposure assessment.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment

EPA used the food consumption data from the USDA 2003–2008 NHANES/WWEIA. As to residue levels in food, EPA used tolerance levels and 100 PCT for the chronic dietary exposure assessment.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that topramezone does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and Percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for topramezone. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used the highest drinking water concentration expected to result from the currently-registered use of topramezone for direct, aquatic applications. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

For acute and chronic dietary risk assessments, the water concentration value of 45 ppb was used to assess the contribution to drinking water, based on the maximum allowable topramezone concentration in water bodies with potable water intakes from direct aquatic use.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Topramezone is currently registered for turf and golf course uses that could result in residential exposures. Topramezone is also currently registered for use in direct aquatic applications that could result in exposure during recreational swimming activities. The following residential exposure scenarios were used for assessing aggregate exposures: Short-

term dermal post-application exposure resulting from the physical activities on turf for adults, short-term dermal and incidental oral (hand-to-mouth) post-application exposures resulting from the physical activities on turf for children 1 < 2 years, and intermediate-term incidental oral exposure resulting from soil ingestion from turf use for children 1 < 2 years. These post-application exposure estimates from the turf use are protective of post-application exposure for older children more likely to engage in recreational swimming activities. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.”

EPA has not found topramezone to share a common mechanism of toxicity with any other substances, and topramezone does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that topramezone does not have a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA’s Web site at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different

additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There was evidence of increased quantitative prenatal susceptibility following *in utero* exposures to rats and rabbits. Fetal skeletal variations and abnormalities were observed in all of the rat and rabbit developmental studies, typically in the absence of maternal toxicity or in the presence of less severe maternal effects. Increased qualitative susceptibility was also observed in the developmental neurotoxicity study where offspring neurobehavioral and neuropathological changes were observed in the presence of limited maternal toxicity (corneal opacity). Concern is low since the effects are well-characterized and endpoints selected for risk assessment are protective of all observed offspring effects. There was no evidence of increased offspring sensitivity in the two-generation rat reproduction toxicity study.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X for all exposure scenarios except for acute dietary exposure. The FQPA SF of 10X was retained for acute dietary exposure to account for the extrapolation of a NOAEL from a LOAEL. This decision is based on the following findings:

i. The toxicity database for topramezone is adequate to assess the risk of aggregate exposure to topramezone. While a subchronic inhalation study is not available for topramezone, EPA concluded, using a weight-of-evidence approach, that this study is not required at this time.

ii. Although there was evidence of potential neurotoxicity in the developmental neurotoxicity study (e.g., changes in neurobehavioral and neuropathological observations in offspring), there was no additional evidence of neurotoxicity in the rest of the toxicological database and the selected endpoints are protective of the observed effect up to the limit dose.

iii. Although there was evidence of increased prenatal susceptibility as discussed in Unit III.D.2., there are clear NOAELs associated with those effects, and the Agency’s selected points of departure are protective of those effects. Therefore, there is no need to retain the FQPA 10X SF to adequately protect infants and children from these effects.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and

tolerance-level residues. The maximum allowable concentration in potable water intakes was used to assess exposure to topramezone in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by topramezone.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to topramezone will occupy 98% of the aPAD for all infants less than 1 year old, the population group receiving the greatest exposure, and 50% of the aPAD for females 13–49 years old.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to topramezone from food and water will utilize 62% of the cPAD for all infants less than 1-year-old, the population group receiving the greatest exposure.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Topramezone is currently registered for residential turf uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to topramezone. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 220 for adults and 120 for children 1–2 years old (a subgroup predicted to have the highest residential and aggregate exposure). Because EPA’s level of concern for topramezone is a MOE of

100 or below, these MOEs are not of concern.

4. Intermediate-term risk.

Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Topramezone is currently registered for turf uses that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to topramezone for children that are 1–2 years old that may ingest soil on treated turf. Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in an aggregate MOE of 270 for children 1–2 years old. Because EPA's level of concern for topramezone is a MOE of 100 or below, this MOE is not of concern.

5. *Aggregate cancer risk for U.S. population.* EPA has concluded that topramezone does not pose a cancer risk at exposure levels that do not alter thyroid hormone homeostasis. The chronic aggregate assessment, which utilized a cRfD that is protective of those effects did not indicate a chronic risk above EPA's level of concern; therefore, topramezone is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to topramezone residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (liquid chromatography with tandem mass-spectrometry detection (LC/MS/MS), BASF method D0007) is available to enforce the tolerance expression for sugarcane.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint

United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for topramezone in or on sugarcane.

V. Conclusion

Therefore, tolerances are established for residues of topramezone, including its metabolites and degradates, in or on the following commodity. Compliance with the following tolerance levels is to be determined by measuring only topramezone ([3-(4,5-dihydro-3-isoxazolyl)-2-methyl-4-(methylsulfonyl)phenyl](5-hydroxy-1-methyl-1H-pyrazol-4-yl)methanone) in or on the following commodity: Sugarcane, cane at 0.01 ppm.

VI. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory

Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 15, 2017.

Michael L. Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.612, add alphabetically “Sugarcane, cane” in the table in paragraph (a) to read as follows:

§ 180.612 Topramezone; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	*
Sugarcane, cane	0.01
* * * * *	

[FR Doc. 2017-15744 Filed 7-27-17; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2016-0284; FRL-9961-77]

Pseudomonas chlororaphis strain AFS009; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of *Pseudomonas chlororaphis* strain AFS009 in or on all food commodities when used in accordance with label directions and good agricultural practices. AFS009 Plant Protection, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Pseudomonas chlororaphis* strain AFS009 under FFDCA.

DATES: This regulation is effective July 28, 2017. Objections and requests for hearings must be received on or before September 26, 2017, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2016-0284, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301

Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

Robert McNally, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: BPPDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2016-0284 in the subject line on the first page of your submission. All objections and requests for a hearing

must be in writing, and must be received by the Hearing Clerk on or before September 26, 2017. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2016-0284, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- **Mail:** OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001.

- **Hand Delivery:** To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Background

In the **Federal Register** of June 22, 2016 (81 FR 40594) (FRL-9947-32), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 5F8410) by AFS009 Plant Protection, Inc., 104 T.W. Alexander Dr., Building 18, Research Triangle Park, NC 27709. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009 in or on all food commodities. That document referenced a summary of the petition prepared by the petitioner AFS009 Plant Protection, Inc., which is available in the docket via <http://www.regulations.gov>. One comment was received on the notice of filing. EPA's response to this comment is discussed in Unit III.C.

Since the time the original notice of filing was published, the petitioner provided additional data on the identity

of the active ingredient to EPA. After reviewing these data, EPA now considers the correct identity of the active ingredient to be *Pseudomonas chlororaphis* strain AFS009 and not *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009. In order to give the public an opportunity to comment on this new information, EPA republished its receipt of this tolerance exemption petition filing with an updated and accurate description in the **Federal Register** of December 20, 2016 (81 FR 92758) (FRL-9956-04) and placed a revised petition from AFS009 Plant Protection, Inc. into the docket. There were no comments received in response to the republished notice of filing.

III. Final Rule

A. EPA's Safety Determination

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance or tolerance exemption and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue" Additionally, FFDCA section 408(b)(2)(D) requires that EPA consider "available information concerning the cumulative effects of [a particular pesticide's] . . . residues and other substances that have a common mechanism of toxicity."

EPA evaluated the available toxicological and exposure data on *Pseudomonas chlororaphis* strain AFS009 and considered its validity, completeness, and reliability, as well as the relationship of this information to human risk. A full explanation of the data upon which EPA relied and its

assessments based on those data can be found within the June 1, 2017, document entitled "Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for *Pseudomonas chlororaphis* strain AFS009." This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

Based upon its evaluation, EPA concludes that *Pseudomonas chlororaphis* strain AFS009 is not likely to be toxic, is not pathogenic, and is not infective. Although there may be some exposure to residues when used on all food commodities in accordance with label directions and good agricultural practices, there is a lack of concern due to the lack of potential for adverse effects. EPA also determined that retention of the Food Quality Protection Act (FQPA) safety factor was not necessary as part of the qualitative assessment conducted for *Pseudomonas chlororaphis* strain AFS009.

Based upon its evaluation, EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of *Pseudomonas chlororaphis* strain AFS009. Therefore, an exemption from the requirement of a tolerance is established for residues of *Pseudomonas chlororaphis* strain AFS009 in or on all food commodities when used in accordance with label directions and good agricultural practices.

B. Analytical Enforcement Methodology

Due to the lack of toxicity, infectivity, and pathogenicity of *Pseudomonas chlororaphis* strain AFS009, EPA has determined that there is no need for an analytical method to measure and detect residues in or on food.

C. Response to Comments

One comment on the Notice of Filing was received. That comment opposed allowing residues of this pesticide on food but provided no additional information to support a conclusion that the substance is unsafe. EPA evaluated the available information on *Pseudomonas chlororaphis* strain AFS009, including toxicity and potential exposure, and concluded, in accordance with the statutory requirements of the FFDCA, that the exemption would be safe. The commenter has provided no basis for a different conclusion.

IV. Statutory and Executive Order Reviews

This action establishes a tolerance exemption under FFDCA section 408(d)

in response to a petition submitted to EPA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001), or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance exemption in this action, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes. As a result, this action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, EPA has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, EPA has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require

EPA's consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

V. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 23, 2017.

Richard P. Keigwin, Jr.,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Add § 180.1341 to subpart D to read as follows:

§ 180.1341 *Pseudomonas chlororaphis* strain AFS009; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of *Pseudomonas chlororaphis* strain AFS009 in or on all food commodities when used in accordance with label directions and good agricultural practices.

[FR Doc. 2017-15741 Filed 7-27-17; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 424

[CMS-6059-N7]

Medicare, Medicaid, and Children's Health Insurance Programs: Announcement of the Extension of Temporary Moratoria on Enrollment of Part B Non-Emergency Ground Ambulance Suppliers and Home Health Agencies in Designated Geographic Locations

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Extension of temporary moratoria.

SUMMARY: This document announces the extension of statewide temporary moratoria on the enrollment of new Medicare Part B non-emergency ground ambulance providers and suppliers and Medicare home health agencies, subunits, and branch locations in Florida, Illinois, Michigan, Texas, Pennsylvania, and New Jersey, as applicable, to prevent and combat fraud, waste, and abuse. This extension also applies to the enrollment of new non-emergency ground ambulance suppliers and home health agencies, subunits, and branch locations in Medicaid and the Children's Health Insurance Program in those states.

DATES: Applicable July 29, 2017.

FOR FURTHER INFORMATION CONTACT:

Steve Manning, (410) 786-1691.

News media representatives must contact CMS' Public Affairs Office at (202) 690-6145 or email them at press@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

A. CMS' Implementation of Temporary Enrollment Moratoria

Under the Patient Protection and Affordable Care Act (Pub. L. 111-148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) (collectively known as the Affordable Care Act), the Congress provided the Secretary with new tools and resources to combat fraud, waste, and abuse in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). Section 6401(a) of the Affordable Care Act added a new section 1866(j)(7) to the Social Security Act (the Act) to provide the Secretary with authority to impose a temporary moratorium on the enrollment of new

Medicare, Medicaid or CHIP providers and suppliers, including categories of providers and suppliers, if the Secretary determines a moratorium is necessary to prevent or combat fraud, waste, or abuse under these programs. Section 6401(b) of the Affordable Care Act added specific moratorium language applicable to Medicaid at section 1902(kk)(4) of the Act, requiring States to comply with any moratorium imposed by the Secretary unless the State determines that the imposition of such moratorium would adversely impact Medicaid beneficiaries' access to care. Section 6401(c) of the Affordable Care Act amended section 2107(e)(1) of the Act to provide that all of the Medicaid provisions in sections 1902(a)(77) and 1902(kk) are also applicable to CHIP.

In the February 2, 2011 **Federal Register** (76 FR 5862), CMS published a final rule with comment period titled, "Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers," which implemented section 1866(j)(7) of the Act by establishing new regulations at 42 CFR 424.570. Under § 424.570(a)(2)(i) and (iv), CMS, or CMS in consultation with the Department of Health and Human Services' Office of Inspector General (HHS-OIG) or the Department of Justice (DOJ), or both, may impose a temporary moratorium on newly enrolling Medicare providers and suppliers if CMS determines that there is a significant potential for fraud, waste, or abuse with respect to a particular provider or supplier type, or particular geographic locations, or both. At § 424.570(a)(1)(ii), CMS stated that it would announce any temporary moratorium in a **Federal Register** document that includes the rationale for the imposition of such moratorium. This document fulfills that requirement.

In accordance with section 1866(j)(7)(B) of the Act, there is no judicial review under sections 1869 and 1878 of the Act, or otherwise, of the decision to impose a temporary enrollment moratorium. A provider or supplier may use the existing appeal procedures at 42 CFR part 498 to administratively appeal a denial of billing privileges based on the imposition of a temporary moratorium; however, the scope of any such appeal is limited solely to assessing whether the temporary moratorium applies to the provider or supplier appealing the denial. Under § 424.570(c), CMS denies the enrollment application of a provider or supplier if the provider or supplier is subject to a moratorium. If the provider

or supplier was required to pay an application fee, the application fee will be refunded if the application was denied as a result of the imposition of a temporary moratorium (see § 424.514(d)(2)(v)(C)).

Based on this authority and our regulations at § 424.570, we initially imposed moratoria to prevent enrollment of new home health agencies, subunits, and branch locations¹ (hereafter referred to as HHAs) in Miami-Dade County, Florida and Cook County, Illinois, as well as surrounding counties, and Medicare Part B ground ambulance suppliers in Harris County, Texas and surrounding counties, in a notice issued on July 31, 2013 (78 FR 46339).² We exercised this authority again in a notice published on February 4, 2014 (79 FR 6475) when we extended the existing moratoria for an additional 6 months and expanded them to include enrollment of HHAs in Broward County, Florida; Dallas County, Texas; Harris County, Texas; and Wayne County, Michigan and surrounding counties, and enrollment of ground ambulance suppliers in Philadelphia, Pennsylvania and surrounding counties. Then, we further extended these moratoria in documents issued on August 1, 2014 (79 FR 44702), February 2, 2015 (80 FR 5551), July 28, 2015 (80 FR 44967), and February 2, 2016 (81 FR 5444). On August 3, 2016 (81 FR 51120), we extended the current moratoria for an additional 6 months and expanded them to statewide for the enrollment of new HHAs in Florida, Illinois, Michigan, and Texas, and Part B non-emergency ambulance suppliers in New Jersey, Pennsylvania, and Texas. Our August 3, 2016 publication also announced the lifting of temporary moratoria for all Part B emergency ambulance suppliers.³ On January 9,

2017, CMS again issued a document to extend the temporary moratoria for a period of 6 months (82 FR 2363).

B. Determination of the Need for Moratoria

In imposing these enrollment moratoria, CMS considered both qualitative and quantitative factors suggesting a high risk of fraud, waste, or abuse. CMS relied on law enforcement's longstanding experience with ongoing and emerging fraud trends and activities through civil, criminal, and administrative investigations and prosecutions. CMS' determination of a high risk of fraud, waste, or abuse in these provider and supplier types within these geographic locations was then confirmed by CMS' data analysis, which relied on factors the agency identified as strong indicators of risk. (For a more detailed explanation of this determination process and of these authorities, see the July 31, 2013 notice (78 FR 46339) or February 4, 2014 moratoria document (79 FR 6475)).

Because fraud schemes are highly migratory and transitory in nature, many of CMS' program integrity authorities and anti-fraud activities are designed to allow the agency to adapt to emerging fraud in different locations. The laws and regulations governing CMS' moratoria authority give us flexibility to use any and all relevant criteria for future moratoria, and CMS may rely on additional or different criteria as the basis for future moratoria.

1. Application to Medicaid and the Children's Health Insurance Program (CHIP)

The February 2, 2011, final rule also implemented section 1902(kk)(4) of the Act, establishing new Medicaid regulations at § 455.470. Under § 455.470(a)(1) through (3), the Secretary may impose a temporary moratorium, in accordance with § 424.570, on the enrollment of new providers or provider types after consulting with any affected State Medicaid agencies. The State Medicaid agency must impose a temporary moratorium on the enrollment of new providers or provider types identified by the Secretary as posing an increased risk to the Medicaid program unless the State determines that the imposition of such moratorium would adversely affect Medicaid

beneficiaries' access to medical assistance and so notifies the Secretary. The final rule also implemented section 2107(e)(1)(D) of the Act by providing, at § 457.990 of the regulations, that all of the provisions that apply to Medicaid under sections 1902(a)(77) and 1902(kk) of the Act, as well as the implementing regulations, also apply to CHIP.

Section 1866(j)(7) of the Act authorizes imposition of a temporary enrollment moratorium for Medicare, Medicaid, and/or CHIP, "if the Secretary determines such moratorium is necessary to prevent or combat fraud, waste, or abuse under either such program." While there may be exceptions, CMS believes that generally, a category of providers or suppliers that poses a risk to the Medicare program also poses a similar risk to Medicaid and CHIP. Many of the new anti-fraud provisions in the Affordable Care Act reflect this concept of "reciprocal risk" in which a provider that poses a risk to one program poses a risk to the other programs. For example, section 6501 of the Affordable Care Act titled, "Termination of Provider Participation under Medicaid if Terminated Under Medicare or Other State Plan," which amends section 1902(a)(39) of the Act, requires State Medicaid agencies to terminate the participation of an individual or entity if such individual or entity is terminated under Medicare or any other State Medicaid plan. Additional provisions in title VI, Subtitles E and F of the Affordable Care Act also support the determination that categories of providers and suppliers pose the same risk to Medicaid as to Medicare. Section 6401(a) of the Affordable Care Act required us to establish levels of screening for categories of providers and suppliers based on the risk of fraud, waste, and abuse determined by the Secretary. Section 6401(b) of the Affordable Care Act required State Medicaid agencies to screen providers and suppliers based on the same levels established for the Medicare program. This reciprocal concept is also reflected in the Medicare moratoria regulations at § 424.570(a)(2)(ii) and (iii), which permit CMS to impose a Medicare moratorium based solely on a State imposing a Medicaid moratorium. Accordingly, CMS has determined that there is a reasonable basis for concluding that a category of providers or suppliers that poses a risk to Medicare also poses a similar risk to Medicaid and CHIP, and that a moratorium in all of these programs is necessary to effectively combat this risk.

¹ As noted in the preamble to the final rule with comment period implementing the moratorium authority (February 2, 2011, 76 FR 5870), home health agency subunits and branch locations are subject to the moratoria to the same extent as any other newly enrolling home health agency.

² CMS has identified an error in the provider and beneficiary saturation data described in our July 31, 2013 *Federal Register* notice (78 FR 46339). We have subsequently revised the methodology by which we determine provider and beneficiary saturation. Following these revisions to the methodology, we simulated application of our current 2016 methodology to the 2013 data, and determined that the 2013 decision to impose the moratorium would not have been impacted had the revised methodology been applied. Provider saturation remains one of the criteria used to determine whether to implement a moratorium. CMS has made market saturation data publicly available at <https://data.cms.gov/market-saturation>.

³ CMS also concurrently announced a demonstration under the authority provided in section 402(a)(1)(J) of the Social Security Amendments of 1967 (42 U.S.C. 1395b-1(a)(1)(J))

that allows for access to care-based exceptions to the moratoria in certain limited circumstances after a heightened review of that provider has been conducted. This exception process also applies to Medicaid and CHIP providers in each state. This announcement may be found in the *Federal Register* document issued on August 3, 2016 (81 FR 51116).

2. Consultation With Law Enforcement

In consultation with the HHS Office of Inspector General (OIG) and the Department of Justice (DOJ), CMS previously identified two provider and supplier types in nine geographic locations that warrant a temporary enrollment moratorium. For a more detailed discussion of this consultation process, see the July 31, 2013 notice (78 FR 46339) or February 4, 2014 moratoria document (79 FR 6475).

3. Data Analysis

In addition to consulting with law enforcement, CMS also analyzed its own data to identify specific provider and supplier types within geographic locations with significant potential for fraud, waste or abuse, therefore warranting the imposition of enrollment moratoria.

4. Beneficiary Access to Care

Beneficiary access to care in Medicare, Medicaid, and CHIP is of critical importance to CMS and its State partners, and CMS carefully evaluated access for the target moratorium locations with every imposition and extension of the moratoria. Prior to imposing and extending these moratoria, CMS reviewed Medicare data for these areas and found no concerns with beneficiary access to HHAs or ground ambulance suppliers. CMS also consulted with the appropriate State Medicaid Agencies and with the appropriate State Departments of Emergency Medical Services to determine if the moratoria would create access to care concerns for Medicaid and CHIP beneficiaries. All of CMS' State partners were supportive of CMS' analysis and proposals, and together with CMS, determined that continuation of these moratoria would not create access to care issues for Medicaid or CHIP beneficiaries.

5. When a Temporary Moratorium Does Not Apply

Under § 424.570(a)(1)(iii), a temporary moratorium does not apply to any of the following: (1) Changes in practice location (2) changes in provider or supplier information, such as phone number or address; or (3) changes in ownership (except changes in ownership of HHAs that require initial enrollment under § 424.550). Also, in accordance with § 424.570(a)(1)(iv), a temporary moratorium does not apply to any enrollment application that a Medicare contractor has already approved, but has not yet entered into the Provider Enrollment, Chain, and Ownership System (PECOS) at the time the moratorium is imposed.

6. Lifting a Temporary Moratorium

In accordance with § 424.570(b), a temporary enrollment moratorium imposed by CMS will remain in effect for 6 months. If CMS deems it necessary, the moratorium may be extended in 6-month increments. CMS will evaluate whether to extend or lift the moratorium before the end of the initial 6-month period and, if applicable, any subsequent moratorium periods. If one or more of the moratoria announced in this document are extended, CMS will publish a document regarding such extensions in the **Federal Register**.

As provided in § 424.570(d), CMS may lift a moratorium at any time if the President declares an area a disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, if circumstances warranting the imposition of a moratorium have abated, if the Secretary has declared a public health emergency, or if, in the judgment of the Secretary, the moratorium is no longer needed.

Once a moratorium is lifted, the provider or supplier types that were unable to enroll because of the moratorium will be designated to CMS' high screening level under §§ 424.518(c)(3)(iii) and 455.450(e)(2) for 6 months from the date the moratorium was lifted.

II. Extension of Home Health and Ambulance Moratoria—Geographic Locations

CMS currently has in place moratoria on newly enrolling HHAs in Florida, Illinois, Michigan, and Texas and Part B non-emergency ambulance suppliers in New Jersey, Pennsylvania, and Texas.

As provided in § 424.570(b), CMS may deem it necessary to extend previously-imposed moratoria in 6-month increments. Under this authority, CMS is extending the temporary moratoria on the Medicare enrollment of HHAs and Part B non-emergency ground ambulance providers and suppliers in the geographic locations discussed herein. Under the regulations at § 455.470 and § 457.990, these moratoria also apply to the enrollment of HHAs and non-emergency ground ambulance providers and suppliers in Medicaid and CHIP in those locations. Under § 424.570(b), CMS is required to publish a document in the **Federal Register** announcing any extension of a moratorium, and this extension of moratoria document fulfills that requirement.

CMS consulted with the HHS–OIG regarding the extension of the moratoria on new HHAs and Part B non-

emergency ground ambulance providers and suppliers in all of the moratoria states, and HHS–OIG agrees that a significant potential for fraud, waste, and abuse continues to exist regarding those provider and supplier types in these geographic areas. The circumstances warranting the imposition of the moratoria have not yet abated, and CMS has determined that the moratoria are still needed as we monitor the indicators and continue with administrative actions to combat fraud and abuse, such as payment suspensions and revocations of provider/supplier numbers. (For more information regarding the monitored indicators, see the February 4, 2014 moratoria document (79 FR 6475)).

Based upon CMS' consultation with the relevant State Medicaid agencies, CMS has concluded that extending these moratoria will not create an access to care issue for Medicaid or CHIP beneficiaries in the affected states at this time. CMS also reviewed Medicare data for these states and found there are no current problems with access to HHAs or ground ambulance providers or suppliers. Nevertheless, the agency will continue to monitor these locations to make sure that no access to care issues arise in the future.

Based upon our consultation with law enforcement and consideration of the factors and activities described previously, CMS has determined that the temporary enrollment moratoria should be extended for an additional 6 months.

III. Summary of the Moratoria Locations

CMS is executing its authority under sections 1866(j)(7), 1902(kk)(4), and 2107(e)(1)(D) of the Act to extend and implement temporary enrollment moratoria on HHAs for all counties in Florida, Illinois, Michigan, and Texas, as well as Part B non-emergency ground ambulance providers and suppliers for all counties in New Jersey, Pennsylvania, and Texas.

IV. Clarification of Right to Judicial Review

Section 1866(j)(7)(B) of the Act states that there shall be no judicial review under section 1869, section 1878, or otherwise, of a temporary moratorium imposed on the enrollment of new providers of services and suppliers if the Secretary determines that the moratorium is necessary to prevent or combat fraud, waste, or abuse. Accordingly, our regulations at 42 CFR 498.5(l)(4) state that for appeals of denials based on a temporary moratorium, the scope of review will be

limited to whether the temporary moratorium applies to the provider or supplier appealing the denial. The agency's basis for imposing a temporary moratorium is not subject to review. Our regulations do not limit the right to seek judicial review of a final agency decision that the temporary moratorium applies to a particular provider or supplier. In the preamble to the February 2, 2011 (76 FR 5918) final rule with comment period establishing this regulation, we explained that "a provider or supplier may administratively appeal an adverse determination based on the imposition of a temporary moratorium up to and including the Department Appeal Board (DAB) level of review." We are clarifying that providers and suppliers that have received unfavorable decisions in accordance with the limited scope of review described in § 498.5(l)(4) may seek judicial review of those decisions after they exhaust their administrative appeals. However, we reiterate that section 1866(j)(7)(B) of the Act precludes judicial review of the agency's basis for imposing a temporary moratorium.

V. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

VI. Regulatory Impact Statement

CMS has examined the impact of this document as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects, distributive impacts, and equity). A regulatory impact analysis

(RIA) must be prepared for major regulatory actions with economically significant effects (\$100 million or more in any 1 year). This document will prevent the enrollment of new home health providers and Part B non-emergency ground ambulance suppliers in Medicare, Medicaid, and CHIP in certain states. Though savings may accrue by denying enrollments, the monetary amount cannot be quantified. Since the imposition of the initial moratoria on July 31, 2013, more than 1184 HHAs and 23 ambulance companies in all geographic areas affected by the moratoria had their applications denied. We have found the number of applications that are denied after 60 days declines dramatically, as most providers and suppliers will not submit applications during the moratoria period. Therefore, this document does not reach the economic threshold, and thus is not considered a major action.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than \$7.5 million to \$38.5 million in any one year. Individuals and states are not included in the definition of a small entity. CMS is not preparing an analysis for the RFA because it has determined, and the Secretary certifies, that this document will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if an action may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, CMS defines a small rural hospital as a hospital that is located outside of a metropolitan statistical area (MSA) for Medicare payment purposes and has fewer than 100 beds. CMS is not preparing an analysis for section 1102(b) of the Act because it has determined, and the Secretary certifies, that this document will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any regulatory action whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated

annually for inflation. In 2017, that threshold is approximately \$148 million. This document will have no consequential effect on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed regulatory action (and subsequent final action) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Because this document does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this document was reviewed by the Office of Management and Budget.

Dated: July 14, 2017.

Seema Verma

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2017–15961 Filed 7–27–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 161020985–7181–02]

RIN 0648–XF579

Fisheries of the Exclusive Economic Zone Off Alaska; Alaska Plaice in the Bering Sea and Aleutian Islands Management Area

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Alaska plaice in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the 2017 Alaska plaice total allowable catch (TAC) specified for the BSAI.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), July 26, 2017, through 2400 hrs, A.l.t., December 31, 2017.

FOR FURTHER INFORMATION CONTACT: Steve Whitney, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management

Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2017 Alaska plaice TAC specified for the BSAI is 11,050 metric tons as established by the final 2017 and 2018 harvest specifications for groundfish in the BSAI (82 FR 11826, February 27, 2017).

In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS, (Regional Administrator) has determined that the 2017 Alaska plaice TAC in the BSAI will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 10,050 mt, and is setting aside the remaining 1,000 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Alaska plaice in the BSAI.

After the effective date of this closure the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the directed fishery closure of Alaska plaice in the BSAI. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of July 24, 2017.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of

prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

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

Dated: July 25, 2017.

Jennifer M. Wallace,
Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.
[FR Doc. 2017-15930 Filed 7-25-17; 4:15 pm]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 161020985-7181-02]

RIN 0648-XF580

Fisheries of the Exclusive Economic Zone Off Alaska; "Other Flatfish" in the Bering Sea and Aleutian Islands Management Area

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for "other flatfish" in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the 2017 "other flatfish" total allowable catch (TAC) specified for the BSAI.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), July 26, 2017, through 2400 hrs, A.l.t., December 31, 2017.

FOR FURTHER INFORMATION CONTACT: Steve Whitney, 907-586-7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2017 "other flatfish" TAC specified for the BSAI is 2,125 metric tons as established by the final 2017 and 2018 harvest specifications for

groundfish in the BSAI (82 FR 11826, February 27, 2017).

In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS, (Regional Administrator) has determined that the 2017 "other flatfish" TAC in the BSAI will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 2,000 mt, and is setting aside the remaining 125 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for "other flatfish" in the BSAI.

After the effective date of this closure the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the directed fishery closure of "other flatfish" in the BSAI. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of July 24, 2017.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

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

Dated: July 25, 2017.

Jennifer M. Wallace,
Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.
[FR Doc. 2017-15941 Filed 7-25-17; 4:15 pm]

BILLING CODE 3510-22-P

Proposed Rules

Federal Register

Vol. 82, No. 144

Friday, July 28, 2017

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2017-0712; Directorate Identifier 2017-NM-014-AD]

RIN 2120-AA64

Airworthiness Directives; Bombardier, Inc., Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede Airworthiness Directive (AD) 2016-13-14, for certain Bombardier, Inc., Model DHC-8-400 series airplanes. AD 2016-13-14 requires an inspection to determine if certain left and right main landing gear (MLG) retract actuator rod ends are installed and repetitive liquid penetrant inspections (LPIs) of affected left and right MLG retract actuator rod ends, and corrective actions if necessary. Since we issued AD 2016-13-14, we have determined that replacement of the left and right MLG is necessary to address the unsafe condition. This proposed AD would retain the actions specified in AD 2016-13-14 and add a replacement of the left and right MLG retract actuator rod ends. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by September 11, 2017.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Fax:* 202-493-2251.
- *Mail:* U.S. Department of

Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590.

- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Bombardier, Inc., Q-Series Technical Help Desk, 123 Garratt Boulevard, Toronto, Ontario M3K 1Y5, Canada; telephone: 416-375-4000; fax: 416-375-4539; email: thd.qseries@aero.bombardier.com; Internet: <http://www.bombardier.com>. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2017-0712; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone: 800-647-5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Aziz Ahmed, Aerospace Engineer, Airframe and Mechanical Systems Branch, ANE-171, FAA, New York Aircraft Certification Office (ACO), 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 516-228-7329; fax: 516-794-5531.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA-2017-0712; Directorate Identifier 2017-NM-014-AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

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

Discussion

On June 22, 2016, we issued AD 2016-13-14, Amendment 39-18579 (81 FR 43481, July 5, 2016) ("AD 2016-13-14"), for certain Bombardier, Inc., Model DHC-8-400 series airplanes. AD 2016-13-14 was prompted by a report of a cracked MLG retract actuator rod end. AD 2016-13-14 requires an inspection to determine if certain left and right MLG retract actuator rod ends are installed and repetitive LPIs of affected left and right MLG retract actuator rod ends, and corrective actions if necessary. AD 2016-13-14 also provides optional terminating action for the inspections. We issued AD 2016-13-14 to detect and correct fatigue cracking of the left and right MLG retract actuator rod ends, which could lead to left or right MLG collapse.

The preamble to AD 2016-13-14 explains that we consider the requirements "interim action" and were considering further rulemaking. We now have determined that further rulemaking is indeed necessary, and this proposed AD follows from that determination.

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian AD CF-2016-16R1, dated June 27, 2016 (referred to after this as the Mandatory Continuing Airworthiness Information, or "the MCAI"), to correct an unsafe condition for certain Bombardier, Inc. Model DHC-8-400 series airplanes. The MCAI states:

There has been a single reported case of a cracked MLG retract actuator rod end in service. A supplier disclosure letter and subsequent Bombardier analysis indicate that the MLG retract actuator rod end P/N [part number] P3A2750 and P3A2750-1 may develop fatigue cracking. This condition, if not corrected, could lead to left hand (LH) or right hand (RH) MLG collapse.

This [Canadian] AD mandates the inspection [to determine if certain left and right main landing gear MLG retract actuator rod ends are installed, repetitive LPIs of affected left and right MLG retract actuator rod ends, and corrective actions if necessary], and replacement of the LH and RH MLG retract actuator rod ends P/N P3A2750 and

P3A2750–1 [which is terminating action for the repetitive LPIs].

This [Canadian] AD was revised to clarify paragraph B. and C. [of this Canadian AD], which specifies when the Liquid Penetrant Inspections (LPI) should begin.

Corrective actions includes replacing cracked MLG retract actuator rod ends. You may examine the MCAI in the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2017–0712.

Related Service Information Under 14 CFR Part 51

Bombardier, Inc. has issued Bombardier Service Bulletin 84–32–142, dated May 4, 2016. This service information describes procedures for an inspection to determine if certain left and right MLG retract actuator rod ends are installed, repetitive LPIs of the left and right MLG retract actuator rod ends, and replacement of left and right MLG retract actuator rod ends. 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.

FAA's Determination and Requirements of This Proposed AD

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

Costs of Compliance

We estimate that this proposed AD affects 52 airplanes of U.S. registry.

The actions required by AD 2016–13–14, and retained in this proposed AD takes about 1 work-hour per product, at an average labor rate of \$85 per work-hour. Based on these figures, the estimated cost of the inspection that is required by AD 2016–13–14 is \$85 per product.

We also estimate that it would take about 3 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is \$85 per work-hour. Required parts would cost about \$2,019 per product. Based on these figures, we estimate the cost of this proposed AD on

U.S. operators to be \$118,248, or \$2,274 per product.

In addition, we estimate that any necessary follow-on actions will take about 3 work-hours and require parts costing \$2,019, for a cost of \$2,274 per product. We have no way of determining the number of aircraft that might 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.

Regulatory Findings

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

- 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2016–13–14, Amendment 39–18579 (81 FR 43481, July 5, 2016), and adding the following new AD:

Bombardier, Inc.: Docket No. FAA–2017–0712; Directorate Identifier 2017–NM–014–AD.

(a) Comments Due Date

We must receive comments by September 11, 2017.

(b) Affected ADs

This AD replaces AD 2016–13–14, Amendment 39–18579 (81 FR 43481, July 5, 2016) ("AD 2016–13–14").

(c) Applicability

This AD applies to Bombardier, Inc., Model DHC–8–400, –401 and –402 airplanes, certificated in any category, serial numbers 4001, and 4003 through 4325 inclusive.

(d) Subject

Air Transport Association (ATA) of America Code 32, Landing gear.

(e) Reason

This AD was prompted by a report of a cracked main landing gear (MLG) retract actuator rod end. We are issuing this AD to detect and correct fatigue cracking of the left and right MLG retract actuator rod ends, which could lead to left or right MLG collapse.

(f) Compliance

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

(g) Retained Part Number Inspection, With No Changes

This paragraph restates the requirements of paragraph (g) of AD 2016–13–14, with no changes. Within 100 flight cycles after July 20, 2016 (the effective date of AD 2016–13–14), inspect the left and right MLG retract actuator rod ends to determine if part number (P/N) P3A2750 or P3A2750–1 is installed. A review of airplane maintenance records is acceptable in lieu of this inspection if the part number can be conclusively determined from that review.

(h) Retained Repetitive Liquid Penetrant Inspections (LPIs), With No Changes

This paragraph restates the requirements of paragraph (h) of AD 2016–13–14, with no changes. For each left or right MLG retract actuator rod end having P/N P3A2750 or P3A2750–1: At the applicable time specified in paragraph (h)(1) or (h)(2) of this AD, do an LPI to detect cracks of the MLG retract actuator rod end, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 84–32–142, dated May 4, 2016, except as required by paragraph (k) of this AD. Thereafter, repeat the LPI at intervals not to exceed 600 flight cycles.

(1) If the MLG retract actuator rod end has accumulated more than 6,000 flight cycles as of July 20, 2016 (the effective date of AD 2016–13–14): Inspect within 100 flight cycles after July 20, 2016.

(2) If the MLG retract actuator rod end has accumulated 6,000 flight cycles or fewer as of July 20, 2016 (the effective date of AD 2016–13–14): Inspect within 600 flight cycles after July 20, 2016.

(i) Retained Corrective Action, With No Changes

This paragraph restates the requirements of paragraph (i) of AD 2016–13–14, with no changes. If any crack is found during any inspection required by paragraph (h) of this AD, before further flight replace the cracked MLG retract actuator rod end, P/N P3A2750 or P3A2750–1, with a MLG retract actuator rod end, P/N P3A6460 in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 84–32–142, dated May 4, 2016, except as required by paragraph (k) of this AD.

(j) Retained Optional Replacement, With No Changes

This paragraph restates the optional replacement specified in paragraph (j) of AD 2016–13–14, with no changes. Replacement of the left and right side MLG retract actuator rod ends, P/N P3A2750 or P3A2750–1, with left and right MLG retract actuator rod ends, P/N P3A6460, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 84–32–142, dated May 4, 2016, except as required by paragraph (k) of this AD, constitutes terminating action for the actions required by paragraphs (g) and (h) of this AD for that airplane.

(k) Retained Exception, With No Changes

This paragraph restates the requirements of paragraph (k) of AD 2016–13–14, with no changes. If it is not possible to complete all the instructions in Bombardier Service Bulletin 84–32–142, dated May 4, 2016, because of the configuration of the airplane: Before further flight, repair using a method approved by the Manager, New York Aircraft Certification Office (ACO), ANE–170, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier, Inc.'s TCCA Design Approval Organization (DAO).

(l) Retained Parts Installation Prohibition, With No Changes

This paragraph restates the requirements of paragraph (l) of AD 2016–13–14, with no changes. As of July 20, 2016 (the effective

date of AD 2016–13–14), no person may install a left or right MLG retract actuator rod end, P/N P3A2750 or P3A2750–1, on any airplane.

(m) New Requirement of This AD: Replacement

Within 1,800 flight cycles after accomplishing the initial inspection required by paragraph (g) of this AD, replace the left and right side MLG retract actuator rod ends, P/N P3A2750 or P3A2750–1, with left and right MLG retract actuator rod ends, P/N P3A6460, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 84–32–142, dated May 4, 2016, except as required by paragraph (k) of this AD. Accomplishing this replacement terminates the requirements of paragraphs (g) and (h) of this AD for that airplane.

(n) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, New York ACO, ANE–170, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 516–228–7300; fax: 516–794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer*: For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, New York ACO, ANE–170, FAA; or TCCA; or Bombardier Inc.'s TCCA DAO. If approved by the DAO, the approval must include the DAO-authorized signature.

(o) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian AD CF–2016–16R1, dated June 27, 2016, for related information. This MCAI may be found in the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2017–0712.

(2) For more information about this AD, contact Aziz Ahmed, Aerospace Engineer, Airframe and Mechanical Systems Branch, ANE–171, FAA, New York ACO, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 516–228–7329; fax: 516–794–5531.

(3) For service information identified in this AD, contact Bombardier, Inc., Q-Series Technical Help Desk, 123 Garratt Boulevard, Toronto, Ontario M3K 1Y5, Canada; telephone: 416–375–4000; fax: 416–375–4539; email: thd.qseries@aero.bombardier.com; Internet: <http://www.bombardier.com>. You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW.,

Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on July 19, 2017.

Victor Wicklund,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2017–15806 Filed 7–27–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 71**

[Docket No. FAA–2017–0565; Airspace Docket No. 17–AWP–1]

Proposed Establishment of Class D and Class E Airspace, Amendment of Class E Airspace; Truckee, CA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class D airspace, and Class E airspace designated as an extension, and modify Class E airspace extending upward from 700 feet above the surface, at Truckee-Tahoe Airport, Truckee, CA. This airspace redesign is necessary to support standard instrument approach and departure procedures under instrument flight rules (IFR) operations at the airport due to the commissioning of the Truckee-Tahoe Airport Non-Federal Contract Tower. This proposal would enhance the safety and management of IFR operations at the airport.

DATES: Comments must be received on or before September 11, 2017.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: 1–800–647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2017–0565; Airspace Docket No. 17–AWP–1, at the beginning of your comments. You may also submit comments through the Internet at <http://www.regulations.gov>.

FAA Order 7400.11, 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 7400.11A at NARA, call (202) 741-6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Tom Clark, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA 98057; telephone (425) 203-4511.

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 establish Class D and Class E extension airspace at Truckee-Tahoe Airport, Truckee, CA, and amend Class E airspace to support standard instrument approach and departure procedures under instrument flight rules (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. Persons 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-2017-0565; Airspace Docket No. 17-AWP-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 Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 1601 Lind Avenue SW., Renton, WA 98057.

Availability and Summary of Documents Proposed for Incorporation by Reference

This document proposes to amend FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016. FAA Order 7400.11A is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11A 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 establishing Class D airspace, and Class E airspace designated as an extension, and modifying Class E airspace extending upward from 700 feet above the surface, at Truckee-Tahoe Airport, Truckee, CA, to support the commissioning of a Non-

Federal Contract Tower (NFCT), and to support standard instrument approach and departure procedures under IFR operations at the airport.

The Truckee-Tahoe NFCT would initially operate as a part-time, seasonal, air traffic control facility. The associated Class D airspace and Class E extension airspace areas would be effective during the specific dates and times established, in advance by NOTAM. The effective date and time will thereafter be continuously published in the Chart Supplement.

Class D airspace would be established upward from the surface to and including 8,400 feet MSL within a 4.2-mile radius of Truckee-Tahoe Airport.

Class E airspace designated as an extension to a Class D or Class E surface area would be established in two segments approximately 4 miles wide, one extending to approximately 10 miles north, and one 12 miles northwest, of Truckee-Tahoe Airport.

Class E airspace extending upward from 700 feet above the surface (currently located north and northwest of the airport) would be shifted slightly east to precisely align with the RNAV instrument approach procedures to runways 11 and 02. Also, a small area would be expanded north of Truckee-Tahoe Airport to provide controlled airspace for IFR departures using runway 29.

Class D and Class E airspace designations are published in paragraph 5000, 6004, and 6005, respectively, of FAA Order 7400.11A, dated August 3, 2016 and effective September 15, 2016, which is incorporated by reference in 14 CFR 71.1. The Class D and Class E airspace designations 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 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

AWP CA D Truckee, CA [New]

Truckee-Tahoe Airport
(Lat. 39°19'12" N., long. 120°08'22" W.)

That airspace extending upward from the surface to and including 8400 feet MSL within a 4.2-mile radius of Truckee-Tahoe Airport. This Class D surface area is effective during the specific dates and times established, in advance, by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6004 Class E Airspace Designated as an Extension to a Class D or Class E Surface Area.

* * * * *

AWP CA E4 Truckee, CA [New]

Truckee-Tahoe Airport
(Lat. 39°19'12" N., long. 120°08'22" W.)

That airspace within a line beginning at the point where a 279° bearing from the Truckee-Tahoe Airport intersects the 4.2-mile radius of the airport to lat. 39°26'41" N., long. 120°20'43" W., to lat. 39°29'27" N., long. 120°16'17" W., to the point where a 344° bearing from the airport intersects the 4.2-mile radius of the airport, thence counter

clockwise along the 4.2-mile radius of the airport to the point of beginning, and that airspace within a line beginning at the point where a 352° bearing from the airport intersects the 4.2-mile radius of the airport to lat. 39°29'18" N., long. 120°06'57" W., to lat. 39°28'11" N., long. 120°01'44" W., to the point where a 053° bearing from the airport intersects the 4.2-mile radius of the airport, thence counter clockwise along the 4.2-mile radius of the airport to the point of beginning.

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

* * * * *

AWP CA E5 Truckee, CA [Modified]

Truckee-Tahoe Airport
(Lat. 39°19'12" N., long. 120°08'22" W.)

That airspace extending upward from 700 feet above the surface within a line beginning at lat. 39°26'41" N., long. 120°20'43" W., to lat. 39°29'27" N., long. 120°16'17" W., to lat. 39°32'45" N., long. 120°18'59" W., to lat. 39°30'34" N., long. 120°23'37" W., thence to the point of beginning; and that airspace within a line beginning at lat. 39°29'18" N., long. 120°06'57" W., to lat. 39°28'11" N., long. 120°01'44" W., to lat. 39°36'17" N., long. 119°58'54" W., to lat. 39°37'23" N., long. 120°04'08" W., thence to the point of beginning; and that airspace within 1.8 miles each side of a line extending from the point where the Truckee-Tahoe Airport 328° bearing intersects the 4.2-mile radius of the airport to the point on a 348° bearing from the airport extending 6.3 miles northwest of the airport.

Issued in Seattle, Washington, on July 19, 2017.

Sam S.L. Shrimpton,

Acting Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2017–15868 Filed 7–27–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2017–0295; Airspace Docket No. 16–AWP–2]

Proposed Establishment of Class E Airspace and Amendment of Class D and E Airspace; Kaunakakai, HI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes changes to airspace designations at Molokai Airport, Kaunakakai, HI. The FAA proposes to establish an area of Class E airspace designated as a surface area; modify Class E airspace designated as an extension to a Class D or E surface

area; and modify Class E airspace extending upward from 700 feet above the surface. Also, this action would update the airport's geographic coordinates for the associated Class D and E airspace areas to reflect the FAA's current aeronautical database and remove references to the Molokai VHF Omnidirectional Range/Tactical Air Navigation (VORTAC). These proposed changes would enhance safety and support Instrument Flight Rules (IFR) operations at the airport.

DATES: Comments must be received on or before September 11, 2017.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: 1 (800) 647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2017–0295; Airspace Docket No. 16–AWP–2, at the beginning of your comments. You may also submit comments through the Internet at <http://www.regulations.gov>.

FAA Order 7400.11A, 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 7400.11A at NARA, call (202) 741–6030, or go to http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Tom Clark, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA 98057; telephone (425) 203–4511.

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 establish Class E airspace and amend Class D and Class E airspace at Molokai Airport, Kaunakakai, HI, in support of 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 (Docket No. FAA–2017–0295; Airspace Docket No. 16–AWP–2) and be submitted in triplicate to DOT Docket Operations (see **ADDRESSES** section for address and phone number).

Persons 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–2017–0295/Airspace Docket No. 16–AWP–2.” The postcard will be date/time stamped and returned to the commenter.

All communications received on or 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 between 8:00 a.m. and 4:30 p.m., Monday through Friday, except federal holidays, at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 1601 Lind Avenue SW., Renton, WA 98057.

Availability and Summary of Documents Proposed for Incorporation by Reference

This document proposes to amend FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016. FAA Order 7400.11A is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11A 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 establishing Class E airspace designated as surface area at Molokai Airport, Kaunakakai, HI. This new airspace designation, within a 4.3 mile radius of the airport, would provide controlled airspace to support increased aircraft operations under IFR during the hours that the Class D airspace area is not in effect.

This proposal also would amend Class E airspace designated as an extension to Class D or E surface area at the airport by increasing the area to a 4.3-mile wide segment (from 3.6 miles wide) extending to 8 miles west (from 7.2 miles west) of the airport. The part-time NOTAM information would also be removed because Class D airspace or Class E surface airspace would be continuous. We would also remove the Molokai VORTAC to reflect the FAA’s transition from ground-based to satellite-based navigation aids.

Additionally, Class E airspace extending upward from 700 feet above the surface would be enlarged west of the airport from the 6.8-mile radius of the airport to an area 10 miles wide (from 3.6 miles wide) extending to 12.4 miles west (from 8.3 miles west).

This proposal would also update the airport’s geographic coordinates for the associated Class D and E airspace areas to reflect the FAA’s current aeronautical database. Lastly, this action would replace the outdated term “Airport/Facility Directory” with the term “Chart

Supplement” in the Class D and E airspace legal descriptions. These modifications are necessary for the safety and management of IFR operations at the airport.

Lastly, a technical amendment would be made to rename the airspace designation for the following airspace areas: AWP HI D Molokai, HI, would be renamed Kaunakakai, HI; AWP HI E2 Molokai, HI, would be renamed Kaunakakai, HI; and AWP HI E5 Molokai, HI, would be renamed Kaunakakai, HI, to remain consistent in the Order.

Class D and Class E airspace designations are published in paragraph 5000, 6002, 6004, and 6005, respectively, of FAA Order 7400.11A, dated August 3, 2016 and effective September 15, 2016, which is incorporated by reference in 14 CFR 71.1. The Class D and Class E airspace designations 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 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

AWP HI D Kaunakakai, HI [Amended]

Molokai Airport, HI
(Lat. 21°09'10" N., long. 157°05'47" W.)

That airspace extending upward from the surface to and including 3,000 feet MSL within a 4.3-mile radius of Molokai Airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6002 Class E Airspace Designated as Surface Areas.

* * * * *

AWP HI E2 Kaunakakai, HI [New]

Molokai Airport, HI
(Lat. 21°09'10" N., long. 157°05'47" W.)

That airspace extending upward from the surface within a 4.3-mile radius of Molokai Airport. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6004 Class E Airspace Areas Designated as an Extension to a Class D or Class E Surface Area.

* * * * *

AWP HI E4 Kaunakakai, HI [Amended]

Molokai Airport, HI
(Lat. 21°09'10" N., long. 157°05'47" W.)

That airspace extending upward from the surface within 1.5 miles north and 2.8 miles south of a 255° bearing from Molokai Airport extending from the 4.3-mile radius to 8 miles west of the airport.

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

* * * * *

AWP HI E5 Kaunakakai, HI [Amended]

Molokai Airport, HI
(Lat. 21°09'10" N., long. 157°05'47" W.)

That airspace extending upward from the surface within a 6.8-mile radius of Molokai Airport and within 5.4 miles north and 4.8 miles south of a 255° bearing from Molokai Airport extending from the 6.8-mile radius to 12.4 miles west of the airport.

Issued in Seattle, Washington, on July 19, 2017.

Sam S.L. Shrimpton,

Acting Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2017–15865 Filed 7–27–17; 8:45 am]

BILLING CODE 4910–13–P

TENNESSEE VALLEY AUTHORITY

18 CFR Part 1318

Procedures for Implementing the National Environmental Policy Act

AGENCY: Tennessee Valley Authority.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Tennessee Valley Authority (TVA) is announcing an extension of the public comment period on its proposed amendments to procedures implementing the National Environmental Policy Act (NEPA). The amendments also address implementation of the Executive Order 13690, Establishing a Federal Flood Risk Management Standard and a Process for Considering Stakeholder Input. A notice of Proposed Rulemaking was published in the **Federal Register** on June 8, 2017, announcing a 60-day comment period closing on August 7, 2017. This document serves to extend the comment period by 30 days until September 6, 2017. TVA is extending the comment period because of the timely requests we received to do so.

DATES: The comment period for the proposed rule published June 8, 2017, at 82 FR 26620, is extended. Comments must be received or postmarked on or before September 6, 2017.

ADDRESSES: Comments can be submitted by one of the following methods:

1. *TVA's NEPA Web site:* <http://www.tva.gov/nepa>. Follow the instructions for submitting comments electronically on the Web site.
2. *Email:* NEPARule@tva.gov.
3. *Mail comments to:* NEPA Rule Comments, Tennessee Valley Authority, 400 W. Summit Hill Drive 11D–K, Knoxville, TN 37902.

Before including your address, phone number, email address, or other personal identifying information in your comment, please note that any comments received, including names and addresses, will become part of the project administrative record and will be available for public inspection.

FOR FURTHER INFORMATION CONTACT:

Matthew Higdon, NEPA Specialist, Tennessee Valley Authority, 400 W. Summit Hill Drive #11D–K, Knoxville, Tennessee 37902. Telephone: 865–632–8051. Email: mshigdon@tva.gov.

SUPPLEMENTARY INFORMATION: On June 8, 2017, TVA published a notice of Proposed Rulemaking in the **Federal Register** (82 FR 26620) to revise TVA's implementing procedures for assessing the effects of TVA's actions in accordance with NEPA, as amended (42 U.S.C. 4321 *et seq.*). TVA requested comments from the public during a 60-day public review period. As discussed in that earlier document, the proposed amendments include: (1) Updates to organizational references to clarify roles and responsibilities within TVA; (2) acknowledgement of the use of modern notification and communication methods to improve public participation; (3) revisions to TVA's list of categorical exclusions to include common actions that have been demonstrated to have little effect on the human environment and to remove categorical exclusions for actions which TVA rarely or no longer undertakes; (4) instructions to incorporate Executive Order 13690; and (5) revisions to improve the clarity of the procedures and remove redundant and outdated information. TVA proposes to publish the amended procedures as rules to be codified in Chapter XIII (Tennessee Valley Authority) as part 1318 of the Code of Federal Regulations (18 CFR part 1318). The key changes to the procedures proposed by TVA are described in detail in the notice.

After publication of the notice, TVA received several requests by stakeholders to extend the comment period to allow for additional time to review the amendments. TVA determined that extending the period by 30 days is appropriate. The TVA Web site listed above contains relevant information relating to the proposed amendments, and TVA urges the public to review this information prior to submitting comments.

Jacinda B. Woodward,

Senior Vice President, Resources and River Management.

[FR Doc. 2017–15983 Filed 7–27–17; 8:45 am]

BILLING CODE 8120–08–P

MILLENNIUM CHALLENGE CORPORATION

22 CFR Part 1305

[MCC FR 17–03]

Touhy Regulations

AGENCY: Millennium Challenge Corporation.

ACTION: Notice of proposed rulemaking.

SUMMARY: The purpose of this document is to provide an update to the outline of the procedures by which the Millennium Challenge Corporation proposes to respond to subpoenas or other official demands for information and testimony served upon itself or its employees.

DATES: Submit comments on or before September 26, 2017.

ADDRESSES: *Send comments to:* Office of the General Counsel, Millennium Challenge Corporation, 1099 14th Street NW., Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: Tamiko N.W. Watkins, Office of the General Counsel, Millennium Challenge Corporation, 1099 14th Street NW., Washington, DC 20005.

SUPPLEMENTARY INFORMATION: The United States Supreme Court held in *United States ex rel. Touhy v. Ragen*, 340 U.S. 462 (1951), that the head of a federal agency may make the determination on his/her sole authority to produce documents and authorize employee's testimony in response to a subpoena or other demand for information. This proposed regulation will govern the Millennium Challenge Corporation's procedures for producing documents authorizing employer testimony in response to a subpoena or other formal demand for information served upon the agency.

List of Subjects in 22 CFR Part 1305

Administrative practice and procedure, Courts, Government employees, Archives and records.

For the reasons set forth above, the Millennium Challenge Corporation proposes to amend Chapter XIII of 22 CFR by revising part 1305 to read as follows:

PART 1305—RELEASE OF OFFICIAL INFORMATION AND TESTIMONY BY MCC PERSONNEL AS WITNESSES

Sec.

1305.1 Purpose and scope.

1305.2 Definitions.

1305.3 Production prohibited unless approved.

1305.4 Factors the General Counsel may consider.

1305.5 Service of demands.

1305.6 Processing demands.

1305.7 Final determination.

1305.8 Restrictions that apply to testimony.

1305.9 Restrictions that apply to released documents.

1305.10 Procedure when a decision is not made prior to the time a response is required.

1305.11 Procedure in the event of an adverse ruling.

1305.12 No private right of action.

Authority: 5 U.S.C. 301.

§ 1305.1 Purpose and scope.

Pursuant to 5 U.S.C. 301, the head of an executive department or military department may prescribe regulations for the government of his/her department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property. Section 301 does not authorize withholding information from the public or limiting the availability of records to the public. This part contains the regulations of the Millennium Challenge Corporation (MCC) concerning procedures to be followed when a request, subpoena, order or other demand (hereinafter in this part referred to as a “demand”) of a court or other authorities in any state or federal proceeding is issued for the production or disclosure of:

(a) Any material contained in the files of MCC;

(b) Any information relating to materials contained in the files of MCC; or

(c) Any information or material acquired by an employee of MCC during the performance of the employee's official duties or because of the employee's official status.

§ 1305.2 Definitions.

For purposes of this part:

(a) *Demand* means a request, order, or subpoena for testimony or documents related to or for possible use in a legal proceeding.

(b) *Document* means any record or other property, no matter what media and including copies thereof, held by MCC, including without limitation, official letters, telegrams, memoranda, reports, studies, calendar and diary entries, maps, graphs, pamphlets, notes, charts, tabulations, analyses, statistical or informational accumulations, any kind of summaries of meetings and conversations, film impressions, magnetic tapes and sound or mechanical reproductions.

(c) *Employee* means all employees and officers of MCC, including contractors who have been appointed by, or are subject to the supervision,

jurisdiction or control of MCC. The procedures established within this part also apply to former employees and contractors of MCC.

(d) *General Counsel* means the General Counsel or MCC employee to whom the General Counsel has delegated authority to act under this subpart.

§ 1305.3 Production prohibited unless approved.

No employee or former employee shall, in response to a demand of a court or other authority, disclose any information relating to materials contained in the files of MCC, or disclose any information or produce any material acquired as part of the performance of the person's official duties, or because of the person's official status, record without the prior, written approval of the General Counsel.

§ 1305.4 Factors the General Counsel may consider.

(a) In deciding whether to authorize the release of official information or the testimony of employees concerning official information, the General Counsel shall consider the following factors:

(1) Whether the demand is unduly burdensome;

(2) MCC's ability to maintain impartiality in conducting its business;

(3) Whether the time and money of the United States would be used for private purposes;

(4) The extent to which the time of employees for conducting official business would be compromised;

(5) Whether the public might misconstrue variances between personal opinions of employees and MCC policy;

(6) Whether the demand demonstrates that the information requested is relevant and material to the action pending, genuinely necessary to the proceeding, unavailable from other sources, and reasonable in its scope;

(7) Whether the number of similar demands would have a cumulative effect on the expenditure of agency resources;

(8) Whether disclosure otherwise would be inappropriate under the circumstances; and

(9) Any other factor that is appropriate.

(b) Among those demands in response to which compliance will not ordinarily be authorized are those with respect to which any of the following factors exists:

(1) The disclosure would violate a statute, Executive order, or regulation;

(2) The integrity of the administrative and deliberative processes of MCC Department would be compromised;

(3) The disclosure would not be appropriate under the rules of procedure governing the case or matter in which the demand arose;

(4) The disclosure, including release in camera, is not appropriate or necessary under the relevant substantive law concerning privilege;

(5) The disclosure, except when in camera and necessary to assert a claim of privilege, would reveal information properly classified or other matters exempt from unrestricted disclosure; or

(6) The disclosure would interfere with ongoing enforcement proceedings, compromise constitutional rights, reveal the identity of an intelligence source or confidential informant, or disclose trade secrets or similarly confidential commercial or financial information.

§ 1305.5 Service of demands.

Demands for official documents, information or testimony must be in writing, and served on the General Counsel, Millennium Challenge Corporation, 1099 14th Street NW., Washington, DC 20005.

§ 1305.6 Processing demands.

(a) After service of a demand to produce or disclose official documents and information, the General Counsel will review the demand and, in accordance with the provisions of this subpart, determine whether, or under what conditions, to authorize the employee to testify on matters relating to official information and/or produce official documents.

(b) If information or material is sought by a demand in any case or matter in which MCC is not a party, an affidavit or, if that is not feasible, a statement by the party seeking the information or material, or by his/her attorney setting forth a summary of the information or material sought and its relevance to the proceeding, must be submitted before a decision is made as to whether materials will be produced or permission to testify or otherwise provide information will be granted. Any authorization for testimony by a present or former employee of MCC shall be limited to the scope of the demand.

(c) When necessary, the General Counsel will coordinate with the Department of Justice to file appropriate motions, including motions to remove the matter to Federal court, to quash, or to obtain a protective order.

(d) If a demand fails to follow the requirements of these regulations, MCC will not allow the testimony or produce the documents.

(e) MCC will process demands in the order in which they are received. Absent unusual circumstances, MCC

will respond within 45 days of the date that the demand was received. The time for response will depend upon the scope of the demand.

(f) The General Counsel may grant a waiver of any procedure described by this subpart where a waiver is considered necessary to promote a significant interest of MCC or the United States or for other good cause.

§ 1305.7 Final determination.

The General Counsel makes the final determination on demands to employees for production of official documents and information or testimony. All final determinations are within the sole discretion of the General Counsel. The General Counsel will notify the requester and the Court or other authority of the final determination, the reasons for the grant or denial of the demand, and any conditions that the General Counsel may impose on the release of documents, or on the testimony of an employee. When in doubt about the propriety of granting or denying a demand for testimony or documents, the General Counsel should consult with the Department of Justice.

§ 1305.8 Restrictions that apply to testimony.

(a) The General Counsel may impose conditions or restrictions on the testimony of MCC employees including, for example, limiting the areas of testimony or requiring the requester and other parties to the legal proceeding to agree that the transcript of the testimony will be kept under seal or will only be used or made available in the particular legal proceeding for which testimony was requested. The General Counsel may also require a copy of the transcript of testimony at the requester's expense.

(b) MCC may offer the employee's declaration in lieu of testimony, in whatever form the court finds acceptable.

(c) If authorized to testify pursuant to this part, an employee may testify to relevant unclassified materials or information within his or her personal knowledge, but, unless specifically authorized to do so by the General Counsel, the employee shall not:

(1) Disclose confidential or privileged information; or

(2) For a current MCC employee, testify as an expert or opinion witness with regard to any matter arising out of the employee's official duties or the functions of MCC, unless testimony is being given on behalf of the United States.

§ 1305.9 Restrictions that apply to released documents.

(a) The General Counsel may impose conditions or restrictions on the release of official documents and information, including the requirement that parties to the proceeding obtain a protective order or execute a confidentiality agreement to limit access and any further disclosure. The terms of the protective order or of the confidentiality agreement must be acceptable to the General Counsel. In cases where protective orders or confidentiality agreements have already been executed, MCC may condition the release of official documents and information on an amendment to the existing protective order or confidentiality agreement.

(b) If the General Counsel so determines, original MCC documents may be presented in response to a demand, but they are not to be presented as evidence or otherwise used in a manner by which they could lose their identity as official MCC documents nor are they to be marked or altered. In lieu of original records, certified copies will be presented for evidentiary purposes. (See 28 U.S.C. 1733).

§ 1305.10 Procedure when a decision is not made prior to the time a response is required.

If a response to a demand is required before the General Counsel can make the determination referred to above, the General Counsel, when necessary, will provide the court or other competent authority with a copy of this part, inform the court or other competent authority that the demand is being reviewed, and respectfully seek a stay of the demand pending a final determination.

§ 1305.11 Procedure in the event of an adverse ruling.

If the court or other competent authority declines to stay the demand in response to a request made in accordance with § 1305.10, or if the court or other competent authority rules that the demand must be complied with irrespective of the instructions from the General Counsel not to produce the material or disclose the information sought, the employee or former employee upon whom the demand has been made shall respectfully decline to comply with the demand (*United States ex rel. Touhy v. Ragen*, 340 U.S. 462 (1951)).

§ 1305.12 No private right of action.

This part is intended only to provide guidance for the internal operations of MCC, and is not intended to, and does not, and may not be relied upon, to create a right or benefit, substantive or

procedural, enforceable at law by a party against the United States.

Dated: June 27, 2017.

Thomas G. Hohenthauer,
Vice President, General Counsel and Corporate Secretary (Acting), Millennium Challenge Corporation.

[FR Doc. 2017-13922 Filed 7-27-17; 8:45 am]

BILLING CODE 9211-03-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2017-0645]

RIN 1625-AA87

Security Zone; Los Angeles Fleet Week, San Pedro, California

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The U.S. Coast Guard proposes establishing a security zone in the Port of Los Angeles Main Channel, in support of Los Angeles Fleet Week. This action is necessary to protect the area surrounding the LA World Cruise Center and the high concentration of people attending the event. This proposed rulemaking is necessary to prohibit vessels from entering into, transiting through, or remaining within the designated area unless specifically authorized by the Captain of the Port, Los Angeles-Long Beach, or her designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before August 21, 2017.

ADDRESSES: You may submit comments identified by docket number USCG-2017-0645 using the Federal eRulemaking Portal at <http://www.regulations.gov>. See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email BMC James Morgia, Waterways Management, U.S. Coast Guard Sector Los Angeles-Long Beach; telephone (310) 521-3860, email James.M.Morgia@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations

DHS Department of Homeland Security
E.O. Executive order
FR Federal Register
LLNR Light List Number
NPRM Notice of proposed rulemaking
Pub. L. Public Law
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

The Port of Los Angeles and the City of Los Angeles Fleet Week Committee has notified the Coast Guard that it will be conducting an annual LA Fleet Week event at the LA World Cruise Center, Berth 90-93, annually for a period of seven days around the Labor Day holiday weekend. The event at the LA World Cruise Center is expected to generate over 250,000 people in attendance each year. Hazards associated with event security may arise due to the expected high concentration of people in attendance for the event, including potential visits from dignitaries and VIP participants, within the main shipping channel of the nation's most economically vital port complex. There is increased awareness regarding recent national and worldwide events that have demonstrated direct threats to the security of large crowds in attendance for various high profile events. The Captain of the Port Los Angeles-Long Beach has determined that potential hazards associated with the number of people expected to be in attendance on the vessels and pier within LA Harbor are a significant concern for public security.

The purpose of this rulemaking is to ensure the safety of, and reduce the risk to, the persons in attendance for LA Fleet Week. The Coast Guard proposes this rulemaking under the authority of 33 U.S.C. 1231.

III. Discussion of Proposed Rule

The COTP proposes to establish a security zone for 7 days during the Labor Day holiday weekend in August and September during the Fleet Week. The security zone would encompass all navigable waters from the surface to the sea floor consisting of a line connecting the following coordinates: 33°44.967' N., 118°16.664' W.; 33°44.874' N., 118°16.362' W.; 33°44.662' N., 118°16.454' W.; 33°44.370' N., 118°16.580' W.; and 33°44.386' N., 118°16.696' W. All coordinates displayed are referenced by North American Datum of 1983, World Geodetic System, 1984. During the enforcement period, vessels are prohibited from entering into, transiting through, or remaining within the designated area unless authorized by the

Captain of the Port or her designated representative. General boating public would be notified prior to the enforcement of the security zone via Broadcast Notice to Mariners. The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and executive orders (E.O.s) related to rulemaking. Below we summarize our analyses based on a number of these statutes and E.O.s, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This NPRM has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, and duration of the security zone. Commercial vessel traffic will be able to safely transit through this security zone, which will impact a designated area of the LA main channel in the vicinity of the World Cruise Center Berth 90-93. The Coast Guard and Inter Agency Unified Command will establish communications with the LA Pilots and Vessel Traffic Service/Marine Exchange to coordinate and mitigate all inbound and outbound commercial traffic movements through the security zone. Recreational traffic will be able to transit around this security zone, which extends 200 yds into the LA main channel leaving 150 to 200 yds of transit area for small vessel traffic to pass around the security 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 security zone may be small entities, for the reasons stated in section IV.A above, this rule will not have a significant economic impact on any vessel owner or operator. If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

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

Also, this proposed rule does not have tribal implications under E.O. 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 an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves a security zone encompassing an area around the Los Angeles Fleet Week events. Such actions are categorically excluded from further review under paragraph 34(g) of Figure 2–1 of Commandant Instruction M16475.ID. A Record of Environmental Consideration supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you

submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at <http://www.regulations.gov>. If your material cannot be submitted using <http://www.regulations.gov>, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to <http://www.regulations.gov> and will include any personal information you have provided. For more about privacy and the docket, visit <http://www.regulations.gov/privacyNotice>.

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at <http://www.regulations.gov> and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

- 2. Add § 165.1189 to read as follows:

§ 165.1189 Security Zone; Los Angeles Fleet Week, San Pedro, California.

(a) *Location.* The following area is a security zone: All navigable waters from the surface to the sea floor consisting of a line connecting the following coordinates: 33°44.967' N., 118°16.664' W.; 33°44.874' N., 118°16.362' W.; 33°44.662' N., 118°16.454' W.; 33°44.370' N., 118°16.580' W.; and 33°44.386' N., 118°16.696' W. All coordinates displayed are referenced by North American Datum of 1983, World Geodetic System, 1984.

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

Designated representative means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Los Angeles-Long Beach (COTP) in the enforcement of the security zone.

(c) *Regulations.* (1) Under the general security zone regulations in subpart D of this part, you may not enter the security zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, hail Coast Guard Sector Los Angeles-Long Beach on VHF-FM Channel 16 or call at (310) 521-3801. Those in the security zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* The security zone will be enforced annually for a period of seven days around the Labor Day holiday weekend in August and September. During the enforcement period, vessels are prohibited from entering into, transiting through, or remaining within the designated area unless authorized by the Captain of the Port or her designated representative. The Coast Guard will publish a local notice to mariners providing exact dates and times at least 20 days prior to the enforcement of the security zone via Broadcast Notice to Mariners.

Dated: July 21, 2017.

Monica L. Rochester,

Captain, U.S. Coast Guard, Acting Captain of the Port, Los Angeles—Long Beach.

[FR Doc. 2017-15946 Filed 7-27-17; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2017-0414]

RIN 1625-AA00

Safety Zone; Huntington Beach Airshow, Huntington Beach, California

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The U.S. Coast Guard proposes establishing a safety zone offshore of Huntington Beach, CA, in support of the Huntington Beach Airshow. This action is necessary to provide for the safety of life on these

navigable waters in the area of the aerobatic zone during the performance. This proposed rulemaking would prohibit persons and vessels from entering into, transiting through, or remaining within the designated area unless specifically authorized by the Captain of the Port, Los Angeles-Long Beach, or her designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before August 21, 2017.

ADDRESSES: You may submit comments identified by docket number USCG-2017-0414 using the Federal eRulemaking Portal at <http://www.regulations.gov>. See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email BMC James Morgia, Waterways Management, U.S. Coast Guard Sector Los Angeles-Long Beach; telephone (310) 521-3860, email James.M.Morgia@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR	Code of Federal Regulations
DHS	Department of Homeland Security
E.O.	Executive order
FR	Federal Register
LLNR	Light List Number
NPRM	Notice of proposed rulemaking
Pub. L.	Public Law
§	Section
U.S.C.	United States Code

II. Background Information and Regulatory History

The City of Huntington Beach and Air Support LLC notified the Coast Guard that it will be conducting an annual four-day Air Show in the vicinity of the Huntington Beach Pier in September and October. Hazards associated with navigation safety may arise due to multiple low flying aircrafts flight paths and stunt performances over the waters off Huntington Beach. The Captain of the Port Los Angeles-Long Beach has determined that potential hazards associated with the Air Show performance would be a safety concern for anyone in the vicinity of the Air Show aerobatic performance area.

The purpose of this rulemaking is to ensure the safety of persons or vessels that operate on and in the vicinity of the aerobatic performance. The Coast Guard proposes this rulemaking under the authority of 33 U.S.C. 1231.

III. Discussion of Proposed Rule

The COTP proposes to establish a safety zone that would be enforced for a period of four days in September and October each year. The safety zone would encompass all navigable waters from the surface to the sea floor consisting of a line connecting the following coordinates: 33°38.378' N., 117°58.833' W.; 33°37.972' N., 117°59.200' W.; 33°39.177' N., 118°01.121' W.; and 33°39.583' N., 118°00.753' W.. All coordinates displayed are referenced by North American Datum of 1983, World Geodetic System, 1984. During the enforcement period, vessels would be prohibited from entering into, transiting through, or remaining within the designated area unless authorized by the Captain of the Port or her designated representative. General boating public would be notified prior to the enforcement of the safety zone via Broadcast Notice to Mariners. The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and executive orders (E.O.s) related to rulemaking. Below we summarize our analyses based on a number of these statutes and E.O.s, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

E.O.s 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771, directs agencies to control regulatory costs through a budgeting process." This NPRM has not been designated a "significant regulatory action" under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance, it is exempt from the requirements of E.O. 13771.

This regulatory action determination is based on the size, location, and duration of the safety zone. Vessel traffic would be able to safely transit around this safety zone, which would impact a small designated area of the Huntington Beach shoreline in the vicinity of the Huntington Beach Pier. The size of the zone is the minimum necessary to provide adequate protection for the waterways users, adjoining areas, and the public. Any hardships experienced by persons or vessels are considered minimal

compared to the interest in protecting the public.

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 safety zone may be small entities, for the reasons stated in section IV.A above, this rule will not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This 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 E.O. 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that Order and

have determined that it is consistent with the fundamental federalism principles and preemption requirements described in E.O. 13132.

Also, this proposed rule does not have tribal implications under E.O. 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 proposed 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 an expenditure, we do discuss the effects of this proposed rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves a safety zone encompassing an area of the Air show aerobatic performance box over a 4 day period lasting 8 hours per day. This proposed rule is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of Commandant Instruction M16475.ID. A Record of Environmental Consideration supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at <http://www.regulations.gov>. If your material cannot be submitted using <http://www.regulations.gov>, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to <http://www.regulations.gov> and will include any personal information you have provided. For more about privacy and the docket, visit <http://www.regulations.gov/privacyNotice>.

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at <http://www.regulations.gov> and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5;

Department of Homeland Security Delegation
No. 0170.1.

■ 2. Add § 165.1109 to read as follows:

§ 165.1109 Safety Zone; Huntington Beach Airshow, Huntington Beach, California.

(a) *Location.* The following area is a safety zone: All navigable waters from the surface to the sea floor consisting of a line connecting the following coordinates: 33°38.378' N., 117°58.833' W.; 33°37.972' N., 117°59.200' W.; 33°39.177' N., 118°01.121' W.; and 33°39.583' N., 118°00.753' W. All coordinates displayed are referenced by North American Datum of 1983, World Geodetic System, 1984.

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

Designated representative means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Los Angeles-Long Beach (COTP) in the enforcement of the safety zone.

(c) *Regulations.*

(1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, hail Coast Guard Sector Los Angeles-Long Beach on VHF-FM Channel 16 or call at (310) 521-3801. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* The safety zone will be enforced during airshow demonstrations for 4 days in September and October. The Coast Guard will provide notice regarding specific event dates and times, which will be published in the local notice to mariners at least 20 days prior to the event via Broadcast Notice to Mariners.

Dated: July 21, 2017.

Monica L. Rochester,

Captain, U.S. Coast Guard, Acting Captain of the Port, Los Angeles-Long Beach.

[FR Doc. 2017-15945 Filed 7-27-17; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 4

RIN 2900-AP16

Schedule for Rating Disabilities; The Genitourinary Diseases and Conditions

AGENCY: Department of Veterans Affairs.
ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs proposes to amend the portion of the Schedule for Rating Disabilities that addresses the genitourinary system. The purpose of this change is to update current medical terminology, incorporate medical advances that have occurred since the last review, and provide well-defined criteria in accordance with actual, standard medical clinical practice. The proposed rule reflects the most up-to-date medical knowledge and clinical practice of nephrology and urology specialties, as well as comments from subject matter experts and the public garnered during a public forum held January 27–28, 2011.

DATES: Comments must be received on or before September 26, 2017.

ADDRESSES: Written comments may be submitted through www.Regulations.gov; by mail or hand-delivery to Director, Regulation Policy and Management (00REG), Department of Veterans Affairs, 810 Vermont Avenue NW., Room 1068, Washington, DC 20420; or by fax to (202) 273-9026. Comments should indicate that they are submitted in response to “RIN 2900-AP16—Schedule for Rating Disabilities; The Genitourinary Diseases and Conditions.” Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461-4902 for an appointment. (This is not a toll-free number.) In addition, during the comment period, comments may be viewed online through the Federal Docket Management System at www.Regulations.gov.

FOR FURTHER INFORMATION CONTACT:

Ioulia Vvedenskaya, M.D., M.B.A., Medical Officer, Part 4 VASRD Regulations Staff (211C), Compensation Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 461-9752. (This is not a toll-free telephone number.)

SUPPLEMENTARY INFORMATION: As part of the Department of Veterans Affairs' (VA) ongoing revision of the Schedule for Rating Disabilities (VASRD), VA proposes changes to the portion of the VASRD that addresses the genitourinary system, which was last revised in 1994. See 59 FR 2523 (Jan. 18, 1994); see also 59 FR 46338 (Sep. 8, 1994). Through this revision, VA aims to eliminate ambiguities, include medical conditions not currently in the rating schedule, implement current, well-refined medical criteria, and update terminology to reflect the most recent medical advances.

I. Proposed Changes to § 4.115

Currently, 38 CFR 4.115 (“Nephritis”) does not adequately reflect current concepts of renal and urinary tract disease and conditions. Regardless of specific disease pathology, kidney conditions generally produce the same symptomatology and lead to the same functional impairment. Therefore, for rating purposes, analysis of pathology, such as is currently presented in the first three sentences of § 4.115, is unnecessary and VA proposes to remove this language.

However, VA proposes to retain the remainder of the language in § 4.115, which addresses the assignment of ratings when both renal and cardiovascular conditions are present, but replace the reference to “nephritis” in the first sentence of the proposed revised section with “renal disease” to more accurately reflect the applicability of the provision. VA proposes to retitle this provision as “Co-existence of Renal and Cardiovascular Conditions” to better address the amended content.

II. Proposed Changes to § 4.115a

Under the current VASRD, diseases of the genitourinary system are listed at 38 CFR 4.115b with instructions directing rating personnel to various rating criteria found at 38 CFR 4.115a, when appropriate. The rating criteria in § 4.115a address impairment of the genitourinary system, including renal dysfunction, voiding dysfunction, and infections.

The introductory paragraph in § 4.115a states that when the VASRD refers a decision maker to these areas of dysfunction, only the predominant area of disability will be considered for rating purposes. VA proposes clarifying this statement by noting that distinct disabilities may be assigned separate evaluations under this section, pursuant to the pyramiding provisions in § 4.14. This statement is intended to reflect that when a particular diagnostic code refers to multiple dysfunctions, only the

predominant dysfunction will be evaluated for that diagnostic code. Distinct disabilities resulting in non-overlapping symptoms may be assigned separate evaluations, however.

VA also proposes to make changes to the rating criteria found in § 4.115a; these proposed changes are discussed below.

A. Renal Dysfunction

Currently, VA evaluates renal dysfunction as follows:

A 100 percent evaluation is assigned for any of the following: Requiring regular dialysis, or precluding more than sedentary activity from one of the following: Persistent edema and albuminuria; or, BUN more than 80 mg%; or, creatinine more than 8 mg%; or, markedly decreased function of kidney or other organ systems, especially cardiovascular.

An 80 percent evaluation is assigned for any of the following: Persistent edema and albuminuria with BUN 40 to 80 mg%; or, creatinine 4 to 8 mg%; or, generalized poor health characterized by lethargy, weakness, anorexia, weight loss, or limitation of exertion.

A 60 percent evaluation is assigned for any of the following: Constant albuminuria with some edema; or, definite decrease in kidney function; or, hypertension at least 40 percent disabling under diagnostic code 7101.

A 30 percent evaluation is assigned for any of the following: Albumin constant or recurring with hyaline and granular casts or red blood cells; or, transient or slight edema or hypertension at least 10 percent disabling under diagnostic code 7101.

A 0 percent evaluation is assigned for either albumin and casts with a history of acute nephritis; or, hypertension non-compensable under diagnostic code 7101.

Subjective terms such as “markedly,” “some,” and “slight” contribute to inconsistent evaluation of genitourinary disabilities rated under this criteria. Therefore, VA proposes to replace these subjective criteria with specific objective laboratory findings, such as the glomerular filtration rate (GFR). Modern medicine states the “[GFR] is widely accepted as the best overall measure of kidney function in health and disease.” Nat’l Kidney Found., “K/DOQI Clinical Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification, and Stratification,” Am. J. Kidney Disease 39:S1–S266, S5 (2002), available at https://www.kidney.org/sites/default/files/docs/ckd_evaluation_classification_stratification.pdf (last viewed Oct. 7, 2016). In clinical practice, subject

matter experts have noted an inverse correlation between GFR and functional impairment (e.g., lower GFRs correspond to greater impairment), and individuals with GFRs less than 60 mL/min are considered to have chronic renal disease. Id. at S12. A GFR less than 60 mL/min is also a sign of renal failure. Id. In addition to using the GFR for evaluation purposes, VA also proposes adding a note to the evaluation criteria specifying that GFR, estimated GFR (eGFR), and creatinine based approximations are acceptable for evaluation purposes, as each has been shown to be an adequate indicator of the stage of chronic kidney disease. Id. at S81. The GFR used must be medically appropriate and calculated by a medical professional.

Based on the level of kidney function generally associated with a particular GFR, VA proposes assigning a 100 percent evaluation for a GFR less than 16 mL/min; an 80 percent evaluation for a GFR between 16 and 29 mL/min; a 60 percent evaluation for a GFR between 30 and 59 mL/min; a 30 percent evaluation for a GFR greater than or equal to 60 mL/min with at least one of the following: Albumin/creatinine ratio (ACR) greater than or equal to 2.5 g/gm (nephrotic range proteinuria), or hypertension at least 10 percent disabling under diagnostic code 7101; and a 0 percent evaluation for a GFR greater than or equal to 60 mL/min with at least one of the following: ACR greater than or equal to .03 g/gm but less than or equal to 2.49 g/gm, or hypertension that is non-compensable under diagnostic code 7101. These levels of evaluation correlate to a modified staging classification of chronic kidney disease by the National Kidney Foundation. Id. At the 100 percent evaluation, the designated GFR is associated with kidney failure and, at the 0 percent evaluation, the designated GFR is associated with an increased risk of kidney damage where a diagnosis of chronic kidney disease has been made. Id. Intermediate levels of evaluation at the 30, 60, and 80 percent levels correspond to the remaining stages of chronic kidney disease as they increase in severity as manifest by declining GFR or increasing proteinuria.

Proteinuria is considered in the evaluation of chronic kidney disease at the 30 and 0 percent levels because GFR measures only the ability of the kidneys to filter the blood and does not always provide a complete picture of renal disease. For example, in the early stages of chronic renal disease resulting from kidney damage, GFR may be within the normal range and impairment may be characterized by other diagnostic

abnormalities, such as increased secretion of protein in the urine (proteinuria). Id. at S71. Proteinuria, as measured by increased urinary excretion of albumin, is an early and sensitive marker of kidney damage in many types of chronic kidney disease. Id. at S48, S101. Therefore, VA proposes that an ACR of 2.5 g/gm or greater (also called nephrotic range proteinuria) would warrant a 30 percent evaluation and an ACR of at least 0.03 g/gm but no more than 2.49 g/gm—i.e., urinary albumin that does not reach the level of nephrotic range proteinuria—would warrant a 0 percent evaluation. VA would not eliminate reference to hypertension in the 0 and 30 percent evaluation criteria because sustained elevation of arterial blood pressure may be a consequence of chronic kidney disease. Id. at S125–26.

Finally, a 100 percent evaluation would still be assigned for chronic kidney disease requiring regular, routine dialysis. VA intends to also extend this evaluation to individuals requiring a kidney transplant who may not yet require regular, routine dialysis. Often, a patient with rapidly deteriorating chronic kidney disease will be placed on a transplant list before they require regular, routine dialysis, although dialysis may actually be required before the transplant is performed.

B. Urinary Tract Infection

VA proposes to preserve the existing rating criteria for urinary tract infection with little change. VA does, however, propose to clarify the criteria for a 30 percent evaluation by specifying that drainage would be by stent or nephrostomy tube. This differentiates drainage via catheterization. Stent or nephrostomy tube insertion are surgical procedures and require more intensive medical management than drainage via catheterization. Catheterization is not medically consistent with the remainder of the criteria required for a 30 percent evaluation because the need for catheterization is not generally accompanied by frequent hospitalization (greater than two times/year) or continuous intensive management.

For the 10 percent evaluation, VA proposes to replace the ambiguous phrase “intermittent intensive management” with “suppressive drug therapy lasting six months or longer.” Antibiotic and suppressive medications are typically the treatment used to treat urinary tract infections. Charles Kodner et al., “Recurrent Urinary Tract Infections in Women: Diagnosis and Management,” 82(6) Am. Family Physician 638–43 (2010); B. Lee et al.,

“Methenamine hippurate for preventing urinary tract infections,” The Cochrane Library (Oct. 17, 2012), <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD003265.pub3/abstract> (last visited April 16, 2014). However, the term “intensive management” suggests something beyond short-term courses of antibiotic treatment for urinary tract infections; this is not clear from the current definition. As such, VA intends to replace “intensive management” with the objective criterion of “suppressive drug therapy lasting six months or longer.” As for the length of time selected, suppressive therapy is more appropriate for a chronic infection. B. Lee, *supra*. Recurrent, or chronic, infections are generally defined as two or more infections in six months, and the recommended treatment is six to twelve months of suppressive drug therapy. Kodner, *supra*. Therefore, VA proposes a 10 percent evaluation when there are one to two hospitalizations per year for urinary tract infections, or suppressive drug therapy lasting six months or longer is required.

The addition of a 0 percent evaluation is also proposed and would be applicable if a veteran has urinary tract infections that require suppressive drug therapy for less than 6 months. Under this evaluation, drug suppressive therapy lasting six months or longer is not required. This proposed evaluation would cover cases that are responsive to treatment and/or are not severe enough to require suppressive drug therapy for six months or more. It would also ease field application by specifying non-compensable criteria that can be compared to the criteria warranting a compensable evaluation.

III. Proposed Changes to § 4.115b

A. Diagnostic Codes (DCs) 7508 and 7510

VA proposes to amend these DCs based on a better understanding of the disease process and the impact of treatment. When imbalances occur in the body, substances in urine can form solid pieces within the urinary tract. These pieces are commonly referred to as stones. Nephrolithiasis, to which diagnostic code 7508 currently applies, is another name for kidney stones. Ureterolithiasis (current DC 7510) refers to stones in the ureter, which is the tube that carries urine from the kidney to the bladder.

Regardless of whether the stone is in the kidney or the ureter, symptoms may include abdominal and/or back pain and blood in the urine. This shared symptomology leads to similar functional impairment. Therefore, VA

proposes to delete existing DC 7510 and to evaluate stones in either the kidney or the ureter under diagnostic code 7508.

Nephrocalcinosis, a disorder in which excess calcium accumulates in the kidneys, does not result in symptoms. Rather, if the accumulation of calcium leads to the creation of stones, the stones themselves may cause symptoms. This condition is commonly evaluated under DC 7508 as analogous to nephrolithiasis, and VA proposes that it continue to be evaluated under this code, but that it be expressly added to the diagnostic code for ease of field application. Therefore, to better express the conditions to be evaluated under DC 7508, VA proposes to rename it as “Nephrolithiasis/Ureterolithiasis/Nephrocalcinosis.”

Proposed DC 7508 would provide a 30-percent rating for recurrent stone formation requiring invasive or non-invasive procedures more than two times per year, as current DC 7508 does, but would no longer provide a 30-percent rating for diet or drug therapy, because such therapies have no specific relationship to these disabilities and are widely recommended for the majority of medical diseases and conditions.

B. DCs 7520 Through 7522

Current DCs 7520 and 7521 provide compensation for actual physical removal of the penis or glans. An evaluation of 30 percent is provided when there is removal of half or more of the penis under DC 7520. In addition, a 20 percent evaluation is assigned when there is removal of the glans under DC 7521. Current DCs 7520 and 7521 also permit rating these conditions alternatively as voiding dysfunction in § 4.115a. VA proposes to no longer rate these conditions as voiding dysfunction, which pertains to issues of leakage and frequency and the use of an appliance or absorbent materials. VA also proposes to revise DCs 7520 and 7521 to include a footnote reference to consider entitlement to Special Monthly Compensation (SMC) for loss of a creative organ under § 3.350. This is meant to correct the omission of this note from previous versions of the VASRD. Removal of half or more of the penis, or removal of the glans, may result in loss of a creative organ. Therefore, although consideration of SMC is considered with application of these diagnostic codes under current policy, this change would ensure consistent consideration of SMC for loss of a creative organ.

VA proposes to revise DC 7522 to encompass erectile dysfunction (ED), regardless of etiology. In making this

change, VA intends to retitle this diagnostic code, “Erectile dysfunction.” ED can occur with or without deformity of the penis, and is a symptom of many systemic, psychological, and metabolic diseases. W. Ludwig, “Organic causes of erectile dysfunction in men under 40,” 92(1) *Urologia Internationalis* 1–6 (2014).

VA proposes to no longer provide a 20-percent rating for this condition, whether with or without penile deformity. VA provides disability compensation for conditions that result in reduced earning capacity. 38 U.S.C. 1155. Erectile dysfunction, with or without penile deformity, is not associated with reductions in earning capacity. Therefore, VA proposes to provide a 0 percent evaluation for this condition. Section 4.115b’s footnote regarding consideration of SMC for loss of use a creative organ where warranted would continue to apply to DC 7522.

VA also proposes to add a note clarifying that Peyronie’s disease is not a ratable condition. Peyronie’s disease should not be rated analogously to ED.

C. DC 7524

VA does not propose any substantive changes to current DC 7524. However, it does intend to correct a typographical error in the last sentence of the existing note, which refers to “underscended” rather than “undescended” testis.

D. DCs 7525, 7527, 7533, 7534, and 7537

Currently, each of these diagnostic codes identifies one or more conditions which have similar symptomatology and functional impairment. The conditions identified are not an exclusive list; therefore, other conditions are often rated as analogous to one of these diagnostic codes. To assist the field in ensuring that the appropriate diagnostic criteria is used to evaluate other conditions not currently listed, VA proposes to rename each of these diagnostic codes and/or include a note identifying those conditions not currently listed.

First, VA proposes to rename DC 7525 as “Prostatitis, urethritis, epididymitis, orchitis (unilateral or bilateral), chronic only,” as these diagnoses all refer to urinary tract infections that do not involve the kidneys and have similar symptoms. Prostatitis would not be included in proposed revised DC 7527, “Prostate gland injuries, infections, hypertrophy, postoperative residuals, bladder outlet obstruction,” because it is rarely caused by a bacterial infection and generally results in repeated bladder infections. J. Stevermer et al., “Treatment of Prostatitis,” 61(10) *Am.*

Family Physician 3015–22 (2000). As a result, the diagnoses contained in DC 7527 are not consistent with non-bacterial prostatitis. In addition, the symptoms caused by prostatitis—recurrent bladder infections—are most similar to the diagnoses contained in DC 7525. There is no change to the evaluation criteria for this DC.

VA also proposes to rename DC 7527 to include bladder outlet obstruction, which has the same functional impairment and symptomatology as the other conditions currently encompassed in this code. Bladder outlet obstruction is not included in current DC 7517, “Bladder, injury of,” because this condition is not caused by an injury to the bladder, but is generally caused by another condition, such as benign prostatic hypertrophy (BPH), which is addressed in DC 7527. R. Dmochowski, “Bladder Outlet Obstruction: Etiology and Evaluation,” 7(Supp. 6) Reviews in Urology S3–S13 (2005). In addition, the symptomatology for this condition may include urinary tract infections, rather than only voiding dysfunction, as contemplated by DC 7517. There is no change to the evaluation criteria for this DC.

VA proposes to add a note to DC 7533 to identify some of the most common cystic kidney diseases seen in the veteran population, to include polycystic disease, uremic medullary cystic disease, medullary sponge kidney, and similar conditions such as hereditary nephritis, Alport’s syndrome, cystinosis, primary oxalosis, and Fabry’s disease. M. Bisceglia et al., “Renal cystic diseases: a review,” 13(1) Advances in Anatomic Pathology 26–56 (2006). These diseases are being added as a medical update and would ensure proper field application of this DC. There is no change to the evaluation criteria for this DC.

Regarding DC 7534, which deals with atherosclerotic renal disease, VA proposes to specifically identify another atherosclerotic renal disease—large vessel disease, unspecified. Renal Failure: Diagnosis and Treatment 65 (J. Gary Abuelo ed. 1995). This disease is being added as a medical update and would ensure proper field application of this DC. There is no change to the evaluation criteria.

Finally, VA proposes to amend DC 7537 to identify the most common forms of interstitial nephritis resulting from the high prevalence of the disease, including gouty nephropathy and disorders of calcium metabolism. There is no change to the evaluation criteria.

E. DCs 7539 and 7541

VA proposes to move all conditions contained in DC 7541 to DC 7539, with the exception of renal involvement in diabetes mellitus, to encompass all systemic conditions that impact the kidneys. All of these conditions are, as amyloid diseases, systemic diseases with renal involvement and therefore are more appropriately evaluated under a single DC. For clarity and ease of field application, VA proposes to add a note to DC 7539 to identify all forms of glomerulonephritis, nephritis, and renal vasculitis encountered with systemic diseases. There is no change to the evaluation criteria.

As for renal involvement in diabetes mellitus (e.g., diabetic nephropathy), VA proposes to continue rating this condition separately under DC 7541. Although this condition would also be rated as renal dysfunction, VA finds there is a need to track this particular condition given its incidence and prevalence in the Veteran population, especially with regard to claims related to Agent Orange exposure.

F. DC 7542

Based on modern clinical findings, neurogenic bladder should continue to be rated as a voiding dysfunction. However, due to high rate of urinary tract infections, VA proposes that this condition may be rated as voiding dysfunction or urinary tract infection, whichever is predominant. D. Sauerwein, “Urinary tract infection in patients with neurogenic bladder dysfunction,” 19(6) Int’l J. of Antimicrobial Agents 592–97 (2002).

G. New Proposed DC 7543

VA proposes the introduction of new DC 7543, “Varicocele/Hydrocele,” to reflect related conditions of the urinary tract that have not previously been recognized for disability evaluation purposes. Varicocele is a dilatation of the veins along the cord that receives blood from the testicles. Hydrocele is a collection of fluid in the scrotum.

The medical community now recognizes that these conditions may be associated with a decrease in fertility and, in rare instances, may be associated with infertility. Center for Male Reproductive Medicine and Vasectomy Reversal, “Varicocele Repair,” <http://www.malereproduction.com/male-infertility/treatment/varicocele-repair.php> (last accessed April 16, 2014). As a decrease in fertility, or the existence of infertility, does not cause a reduction in earning capacity, VA proposes to assign a 0 percent evaluation to these conditions. In

instances where there is a clinical finding of infertility, these conditions may support eligibility for SMC due to loss of use of a creative organ. Therefore, to best administer this benefit, VA proposes a diagnostic code for these conditions that provides a 0 percent evaluation. Section 4.115b’s footnote directing consideration of SMC would apply to DC 7543, consistent with the other DCs in the VASRD addressing a creative organ.

H. New Proposed DC 7544

VA proposes the introduction of new DC 7544, “Renal disease caused by viral infection such as HIV, Hepatitis B, and Hepatitis C,” to reflect renal dysfunctions associated with HIV and hepatitis because of increasing prevalence and incidence of diseases caused by these viruses. Perico Norberto et al., “Hepatitis C Infection and Chronic Renal Diseases,” 4(1) Clinical J. Am. Soc’y of Nephrology 207–20 (2009). Hepatitis A, an acute liver disease, does not cause chronic renal disease and is therefore not included in this DC.

VA proposes to evaluate this DC as renal dysfunction under § 4.115a because, when the liver is damaged due to Hepatitis B or C infection, the accumulation of toxins in the blood can damage the kidneys, causing renal dysfunction. HIV-associated renal dysfunctions have several different etiologies, but can include direct HIV infection of the kidney, kidney damage caused by drugs used to treat HIV, and fluid loss caused by various processes associated with the advanced disease process. Moro O. Salifu, “HIV-Associated Nephropathy,” Medscape, <http://emedicine.medscape.com/article/246031-overview> (Vecihi Batuman ed., 2013) (last accessed April 16, 2014).

I. New Proposed DC 7545

VA proposes the introduction of new DC 7545, “Bladder, diverticulum of.” Currently, there is no DC for diverticulum of the bladder and, as such, it is generally evaluated in the field as analogous to fistula of the bladder. A bladder fistula is an abnormal connection between the bladder and another organ of the body (e.g., the bowel). A bladder diverticulum is an abnormal pouch or sac due to weakness in the bladder’s muscular wall that allows a portion of the bladder to protrude. Urology Care Foundation, “Urology A–Z: Bladder Diverticulum,” <http://www.urologyhealth.org/urology/index.cfm?article=111> (last accessed April 16, 2014). The two conditions have dissimilar symptomatology and result in dissimilar functional impairment. A bladder fistula allows

urine to escape the confines of the bladder into another space such as the rectum, or externally, causing urinary leakage. A bladder diverticulum allows urine to remain in the bladder longer, often resulting in infection as well as voiding dysfunction.

The proposed addition of this new DC would ensure that the condition is more appropriately rated. VA proposes to rate DC 7545 as voiding dysfunction or urinary tract infection, whichever is predominant, because these criteria best capture the functional impairment associated with this condition.

Executive Orders 12866 and 13563

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

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

VA’s impact analysis can be found as a supporting document at www.regulations.gov, usually within 48 hours after the rulemaking document is published. Additionally, a copy of this rulemaking and its impact analysis are

available on VA’s Web site at www.va.gov/orpm/, by following the link for VA Regulations Published from FY 2004 Through Fiscal Year to Date.

Regulatory Flexibility Act

The Secretary hereby certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. This proposed rule would directly affect only individuals and would not directly affect any small entities. Therefore, pursuant to 5 U.S.C. 605(b), this proposed rule would be exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Unfunded Mandates

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

Paperwork Reduction Act

This proposed rule contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521).

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance program numbers and titles affected by this document are 64.009, Veterans Medical Care Benefits; 64.104, Pension for Non-Service-Connected Disability for Veterans; 64.109, Veterans Compensation for Service-Connected Disability.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Gina S. Farrissee, Deputy Chief of Staff, Department of Veterans Affairs, approved this document on May 26, 2017, for publication.

Dated: July 21, 2017.

Michael Shores,

*Director, Regulation Policy & Management,
Office of the Secretary, Department of
Veterans Affairs.*

List of Subjects in 38 CFR Part 4

Disability benefits, Pensions, Veterans.

For the reasons set out in the preamble, the Department of Veterans Affairs proposes to amend 38 CFR part 4 as follows:

PART 4—SCHEDULE FOR RATING DISABILITIES

■ 1. The authority citation for part 4 continues to read as follows:

Authority: 38 U.S.C. 1155, unless otherwise noted.

Subpart B—Disability Ratings

■ 2. Revise § 4.115 to read as follows:

§ 4.115 Co-Existence of renal and cardiovascular conditions.

Separate ratings are not to be assigned for disability from disease of the heart and any form of renal disease, on account of the close interrelationships of cardiovascular diseases. If, however, absence of a kidney is the sole renal disability, even if removal was required because of nephritis, the absent kidney and any hypertension or heart disease will be separately rated. Also, in the event that chronic renal disease has progressed to the point where regular dialysis is required, any coexisting hypertension or heart disease will be separately rated.

■ 3. Amend § 4.115a by revising the introductory text and the table entries regarding “Renal dysfunction” and “Urinary tract infection” to read as follows:

§ 4.115a Ratings of the genitourinary system—dysfunctions.

Diseases of the genitourinary system generally result in disabilities related to renal or voiding dysfunctions, infections, or a combination of these. The following section provides descriptions of various levels of disability in each of these symptom areas. Where diagnostic codes refer the decision maker to these specific areas of dysfunction, only the predominant area of dysfunction shall be considered for rating purposes. Distinct disabilities may be evaluated separately under this section, pursuant to § 4.14, if the symptoms do not overlap. Since the areas of dysfunction described below do not cover all symptoms resulting from genitourinary diseases, specific

diagnoses may include a description of symptoms assigned to that diagnosis.

	Rating
Renal dysfunction:	
Chronic kidney disease with glomerular filtration rate (GFR) less than 16 mL/min; or requiring regular, routine dialysis or kidney transplant	100
Chronic kidney disease with GFR 16 to 29 mL/min	80
Chronic kidney disease with GFR 30 to 59 mL/min	60
Chronic kidney disease with GFR ≥60 mL/min with at least one of the following:	
Albumin/creatinine ratio (ACR) ≥2.5 g/gm (nephrotic range proteinuria); or	
Hypertension at least 10 percent disabling under diagnostic code 7101	30
Chronic kidney disease with GFR ≥60 mL/min with at least one of the following:	
Albumin/creatinine ratio (ACR) from 0.03 g/gm to 2.49 g/gm; or	
Hypertension that is non-compensable under diagnostic code 7101	0
Note: GFR, estimated GFR (eGFR), and creatinine based approximations of GFR will be accepted for evaluation purposes under this section when determined to be appropriate and calculated by a medical professional.	
* * * * *	
Urinary tract infection:	
Poor renal function: Rate as renal dysfunction.	
Recurrent symptomatic infection requiring drainage by stent or nephrostomy tube; or requiring greater than 2 hospitalizations per year; or requiring continuous intensive management	30
Recurrent symptomatic infection requiring 1–2 hospitalizations per year or suppressive drug therapy lasting six months or longer	10
Recurrent symptomatic infection not requiring hospitalization, but requiring suppressive drug therapy for less than 6 months	0

■ 4. Amend § 4.115b by:

■ a. Removing diagnostic code 7510.

■ b. Revising diagnostic codes 7508, 7520, 7521, 7522, 7524, 7525, 7527, 7533, 7534, 7537, 7539, 7541, and 7542.

■ c. Adding diagnostic codes 7543, 7544, and 7545.

The revisions and additions read as follows:

§ 4.115b Ratings of the genitourinary system—diagnoses.

	Rating
* * * * *	
7508 Nephrolithiasis/Ureterolithiasis/Nephrocalcinosis:	
Rate as hydronephrosis, except for recurrent stone formation requiring invasive or non-invasive procedures more than two times/year	30
* * * * *	
7520 Penis, removal of half or more	¹ 30
7521 Penis, removal of glans	¹ 20
7522 Erectile dysfunction, with or without penile deformity	¹ 0
Note: Peyronie's disease is not a ratable condition.	
* * * * *	
7524 Testis, removal:	
Both	¹ 30
One	¹ 0
Note: In cases of the removal of one testis as the result of a service-incurred injury or disease, other than an undescended or congenitally undeveloped testis, with the absence or nonfunctioning of the other testis unrelated to service, an evaluation of 30 percent will be assigned for the service-connected testicular loss. Testis, undescended, or congenitally undeveloped is not a ratable disability.	
7525 Prostatitis, urethritis, epididymitis, orchitis (unilateral or bilateral), chronic only:	
Rate as urinary tract infection.	
For tubercular infections: Rate in accordance with §§ 4.88b or 4.89, whichever is appropriate.	
7527 Prostate gland injuries, infections, hypertrophy, postoperative residuals, bladder outlet obstruction:	
Rate as voiding dysfunction or urinary tract infection, whichever is predominant.	
* * * * *	
7533 Cystic diseases of the kidneys:	
Rate as renal dysfunction.	
Note: Cystic diseases of the kidneys include, but are not limited to, polycystic disease, uremic medullary cystic disease, medullary sponge kidney, and similar conditions such as hereditary nephritis, Alport's syndrome, cystinosis, primary oxalosis, and Fabry's disease.	
7534 Atherosclerotic renal disease (renal artery stenosis, atheroembolic renal disease, or large vessel disease, unspecified):	
Rate as renal dysfunction.	
* * * * *	
7537 Interstitial nephritis, including gouty nephropathy, disorders of calcium metabolism:	

	Rating
Rate as renal dysfunction.	
* * * * *	
7539 Renal amyloid disease: Rate as renal dysfunction. Note: This diagnostic code pertains to renal involvement in secondary glomerulonephritis/vasculitis and in other systemic diseases, such as Lupus erythematosus-Systemic lupus erythematosus nephritis, Henoch-Schonlein syndrome, Scleroderma, Hemolytic uremic syndrome, Polyarteritis, Wegener's granulomatosis, other Vasculitis and its derivatives, Goodpasture's syndrome, sickle cell disease, and other secondary glomerulonephritis.	
* * * * *	
7541 Renal involvement in diabetes mellitus type I or II: Rate as renal dysfunction.	
7542 Neurogenic bladder: Rate as voiding dysfunction or urinary tract infection, whichever is predominant.	
7543 Varicocele/Hydrocele	10
7544 Renal disease caused by viral infection such as HIV, Hepatitis B, and Hepatitis C: Rate as renal dysfunction.	
7545 Bladder, diverticulum of: Rate as voiding dysfunction or urinary tract infection, whichever is predominant.	

¹ Review for entitlement to special monthly compensation under § 3.350 of this chapter.

- 5. Amend Appendix A to Part 4 by:
- a. Adding § 4.115. through 7522, 7524, 7525, 7527, 7533, 7534, 7537, 7539, 7541, and 7542. The additions and revisions to read as follows:
 - b. Revising § 4.115a. ■ d. In § 4.115b, adding diagnostic codes 7543 through 7545.
 - c. In § 4.115b, revising the entries for diagnostic codes 7508, 7510, 7520
- Appendix A to Part 4—Table of Amendments and Effective Dates Since 1946**

Section	Diagnostic code No.
* * * * *	
4.115	Retitled and revised [insert <i>effective date of final rule</i>].
4.115a	Re-designated and revised as § 4.115b; new § 4.115a "Ratings of the genitourinary system-dysfunctions" added February 17, 1994; revised [insert <i>effective date of final rule</i>].
4.115b.	
* * * * *	
	7508 Evaluation February 17, 1994; title, criterion [insert <i>effective date of final rule</i>].
* * * * *	
	7510 Evaluation February 17, 1994; removed [insert <i>effective date of final rule</i>].
* * * * *	
	7520 Criterion February 17, 1994; criterion, footnote [insert <i>effective date of final rule</i>].
	7521 Criterion February 17, 1994; criterion, footnote [insert <i>effective date of final rule</i>].
	7522 Criterion September 8, 1994; title, criterion, note [insert <i>effective date of final rule</i>].
* * * * *	
	7524 Note July 6, 1950; evaluation February 17, 1994; evaluation September 8, 1994; note [insert <i>effective date of final rule</i>].
	7525 Criterion March 11, 1969; evaluation February 17, 1994; title [insert <i>effective date of final rule</i>].
* * * * *	
	7527 Criterion February 17, 1994; title [insert <i>effective date of final rule</i>].
* * * * *	
	7533 Added February 17, 1994; title and note [insert <i>effective date of final rule</i>].
	7534 Added February 17, 1994; title [insert <i>effective date of final rule</i>].
* * * * *	
	7537 Added February 17, 1994; title [insert <i>effective date of final rule</i>].
* * * * *	
	7539 Added February 17, 1994; note [insert <i>effective date of final rule</i>].
* * * * *	
	7541 Added February 17, 1994; title [insert <i>effective date of final rule</i>].
	7542 Added February 17, 1994; criterion [insert <i>effective date of final rule</i>].

Section	Diagnostic code No.
	7543 Added [insert effective date of final rule].
	7544 Added [insert effective date of final rule].
	7545 Added [insert effective date of final rule].
*	*

■ 6. Amend Appendix B to Part 4 by:
 ■ a. Revising diagnostic codes 7508, 7522, 7525, 7527, 7533, 7534, 7537, and 7541.

■ b. Removing diagnostic code 7510;
 ■ c. Adding diagnostic codes 7543 through 7545.

The revisions and additions read as follows:

Appendix B to Part 4—Numerical Index of Disabilities

Diagnostic code No.	
The Genitourinary System	
7508	Nephrolithiasis/Ureterolithiasis/Nephrocalcinosis.
7522	Erectile dysfunction.
7525	Prostatitis, urethritis, epididymitis, orchitis (unilateral or bilateral), chronic only.
7527	Prostate gland injuries, infections, hypertrophy, postoperative residuals, bladder outlet obstruction.
7533	Cystic diseases of the kidneys.
7534	Atherosclerotic renal disease (renal artery stenosis, atheroembolic renal disease, or large vessel disease, unspecified).
7537	Interstitial nephritis, including gouty nephropathy, disorders of calcium metabolism.
7541	Renal involvement in diabetes mellitus type I or II.
7543	Varicocele/Hydrocele.
7544	Renal disease caused by viral infection such as HIV, Hepatitis B, and Hepatitis C.
7545	Bladder, diverticulum of.

■ 7. Amend Appendix C to Part 4 by:
 ■ a. Revising the entries for diagnostic codes 7508, 7522, 7525, 7527, 7533, 7537, and 7541.

■ b. Removing the reference to diagnostic code 7510;
 ■ c. Adding diagnostic codes 7543 through 7545.

The revisions and additions read as follows:

Appendix C to Part 4—Alphabetical Index of Disabilities

	Diagnostic code No.
Bladder:	
Diverticulum of	7545
Erectile dysfunction	7522
Interstitial nephritis, including gouty nephropathy, disorders of calcium metabolism	7537
Kidney:	

	Diagnostic code No.
* * * * *	
Cystic diseases of the	7533
* * * * *	
Nephrolithiasis/Ureterolithiasis/Nephrocalcinosis	7508
* * * * *	
Prostate gland injuries, infections, hypertrophy, postoperative residuals, bladder outlet obstruction	7527
Prostatitis, urethritis, epididymitis, orchitis (unilateral or bilateral), chronic only	7525
* * * * *	
Renal:	
* * * * *	
Disease caused by viral infection such as HIV, Hepatitis B, and Hepatitis C	7544
* * * * *	
Involvement in diabetes mellitus type I or II	7541
* * * * *	
Varicocele/Hydrocele	7543
* * * * *	

[FR Doc. 2017–15765 Filed 7–27–17; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2017–0365; FRL–9965–29–
Region 4]

Air Plan Approval; Kentucky; Revisions to Louisville; Definitions

AGENCY: Environmental Protection
Agency (EPA).

ACTION: Proposed rule.

SUMMARY: On August 29, 2012, the Commonwealth of Kentucky, through the Kentucky Division for Air Quality (KDAQ), submitted changes to the Kentucky State Implementation Plan (SIP) on behalf of the Louisville Metro Air Pollution Control District (District). The Environmental Protection Agency (EPA) is proposing to approve a portion of the submission that modifies the District's air quality regulations as incorporated into the SIP. Specifically, the revisions pertain to definitional changes, including the modification of the definition of “volatile organic compounds”. EPA is proposing to approve this portion of the SIP revision because the Commonwealth has demonstrated that these changes are consistent with the Clean Air Act. EPA will act on the other portion of KDAQ's August 29, 2012, submittal in a separate action.

DATES: Written comments must be received on or before August 28, 2017.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2017–0365 at <http://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT:

Nacosta C. Ward, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9140.

Ms. Ward can be reached via electronic mail at ward.nacosta@epa.gov.

SUPPLEMENTARY INFORMATION: In the Final Rules Section of this **Federal Register**, EPA is approving the State's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this document. Any parties interested in commenting on this document should do so at this time.

Dated: July 11, 2017.

V. Anne Heard,

Acting Regional Administrator, Region 4.

[FR Doc. 2017–15738 Filed 7–27–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 52****[EPA-R04-OAR-2017-0021; FRL-9965-24-Region 4]****Air Plan Approval; Georgia; Miscellaneous Revisions****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve changes to portions of State Implementation Plan (SIP) revisions submitted by the State of Georgia, through the Georgia Department of Natural Resources' Environmental Protection Division, on November 29, 2010, and on July 25, 2014. These changes correct a numbering error, clarify rule applicability, and remove obsolete tables and references in multiple rules. EPA is proposing to approve portions of these SIP revisions because the State has demonstrated that these changes are consistent with the Clean Air Act.

DATES: Written comments must be received on or before August 28, 2017.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R04-OAR-2017-0021 at <http://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT: Richard Wong, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S.

Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303-8960. Mr. Wong can be reached via telephone at (404) 562-8726 or via electronic mail at wong.richard@epa.gov.

SUPPLEMENTARY INFORMATION: In the Final Rules Section of this **Federal Register**, EPA is approving the State's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this document. Any parties interested in commenting on this document should do so at this time.

Dated: July 12, 2017.

V. Anne Heard.

Regional Administrator, Region 4.

[FR Doc. 2017-15739 Filed 7-27-17; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 52****[EPA-R09-OAR-2016-0524; FRL-9965-46-Region 9]****Approval of California Air Plan Revisions, Antelope Valley Air Quality Management District****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve and conditionally approve revisions to the Antelope Valley Air Quality Management District (AVAQMD or "District") portion of the California State Implementation Plan (SIP). These revisions concern the District's demonstration regarding Reasonably Available Control Technology (RACT) requirements for the 1997 8-hour ozone and the 2008 8-hour ozone National Ambient Air Quality Standards (NAAQS or "standard") in the Antelope Valley ozone nonattainment area. The EPA previously proposed to partially approve and partially disapprove AVAQMD's RACT SIP submittals for the 1997 and 2008 8-hour ozone NAAQS

(2006 and 2015 RACT SIPs) because we found that existing District rules implemented RACT for many, but not all, applicable sources. The AVAQMD has since addressed or committed to address these deficiencies. Therefore, we withdraw our previous proposed partial approval and partial disapproval of the AVAQMD 2006 and 2015 RACT SIPs, and now propose to partially approve and partially conditionally approve them into the California SIP. The EPA is also proposing to approve AVAQMD negative declarations into the SIP for the 1997 and the 2008 ozone standards.

We are proposing action on local SIP revisions under the Clean Air Act (CAA or Act). We are taking comments on this proposal and plan to follow with a final action.

DATES: Any comments must arrive by August 28, 2017.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R09-OAR-2016-0524 at <https://www.regulations.gov/>, or via email to Nancy Levin, Rulemaking Office at levin.nancy@epa.gov. For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be removed or edited from *Regulations.gov*. For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the Web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT: Nancy Levin, EPA Region IX, (415) 942-3848, levin.nancy@epa.gov.

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

Table of Contents

- I. The State's Submittal
- A. What documents did the State submit?
 - B. Are there other versions of these documents?
 - C. What is the purpose of the submitted documents?
- II. The EPA's Evaluation and Proposed Action

- A. How is the EPA evaluating the submitted documents?
 - B. Do the documents meet the evaluation criteria?
 - C. EPA recommendations to further improve the RACT SIPs
 - D. Public comment and proposed action
- III. Statutory and Executive Order Reviews

I. The State's Submittal**A. What documents did the State submit?**

Table 1 lists the documents addressed by this proposal with the dates that they were adopted by the local air agency and submitted by the California Air Resources Board (CARB).

TABLE 1—SUBMITTED DOCUMENTS

Local agency	Document	Adopted	Submitted
AVAQMD	AVAQMD 8-Hour Reasonably Available Control Technology—State Implementation Plan Analysis (RACT SIP Analysis)—1997 8-hour Ozone NAAQS “2006 RACT SIP”.	09/19/06	01/31/07
AVAQMD	AVAQMD 8-Hour Reasonably Available Control Technology—State Implementation Plan Analysis (2015 RACT SIP Analysis)—2008 8-hour Ozone NAAQS “2015 RACT SIP”.	07/21/15	10/23/15
AVAQMD	AVAQMD Federal Negative Declarations for Twenty Control Techniques Guidelines Source Categories.	07/21/15	10/23/15
AVAQMD	AVAQMD Federal Negative Declarations for Seven Control Techniques Guidelines Source Categories.	12/20/16	06/07/17

In addition to these SIP submittals, the District and CARB transmitted commitment letters to EPA to adopt and submit specific enforceable measures within a year of our final action that would remedy the deficiencies we identified in our December 15, 2016 proposed partial approval and partial disapproval.^{1 2}

On July 31, 2007, the submittal for AVAQMD's 2006 RACT SIP for the 1997 8-hour ozone NAAQS was deemed by operation of law to meet the completeness criteria in Title 40 of the Code of Federal Regulations (CFR) part 51 Appendix V, which must be met before formal EPA review. On March 9, 2016, the submittal for the AVAQMD's 2015 RACT SIP for the 2008 8-hour ozone NAAQS, including Federal Negative Declarations for Twenty Control Techniques Guidelines Source Categories, was found to meet the completeness criteria. On June 23, 2017, the EPA found that the submittal of AVAQMD's Federal Negative Declarations for Seven Control Techniques Guidelines Source Categories met the completeness criteria.

B. Are there other versions of these documents?

There are no previous versions of these documents in the AVAQMD

portion of the California SIP for the 1997 or 2008 8-hour ozone standards.

C. What is the purpose of the submitted documents?

Volatile Organic Compounds (VOCs) and nitrogen oxides (NO_x) help produce ground-level ozone and smog, which harm human health and the environment. Section 110(a) of the CAA requires states to submit regulations that control VOC and NO_x emissions. Sections 182(b)(2) and (f) require that SIPs for ozone nonattainment areas classified as moderate or above implement RACT for any source covered by a “Control Techniques Guidelines” (CTG) document and for any major source of VOCs or NO_x. The AVAQMD is subject to this requirement as it was previously designated and classified as a moderate nonattainment area for the 1997 NAAQS and is currently classified as a severe-15 ozone nonattainment area for the 1997 and the 2008 8-hour ozone NAAQS.³ Therefore,

³ 40 CFR 81.305; 69 FR 23858 at 23884 (April 30, 2004) (final rule designating and classifying Antelope Valley as a subpart 2/moderate nonattainment for the 1997 8-hour ozone NAAQS); 77 FR 26950 (May 8, 2012) (final rule reclassifying Antelope Valley as severe-15 nonattainment for the 1997 8-hour ozone NAAQS); and 77 FR 30088 at 30100 (May 21, 2012) (final rule designating and classifying Antelope Valley as severe-15 nonattainment for the 2008 8-hour ozone NAAQS). Antelope Valley AQMD is listed in the final rulemaking under “Los Angeles-San Bernardino Cos (W Mojave Desert), CA: Los Angeles County (part).” The EPA evaluated AVAQMD's 2006 RACT SIP submittal as a moderate ozone nonattainment area since the District adopted its 2006 certification based on that classification. On March 13, 2014, the AVAQMD provided additional information to supplement its 2006 RACT SIP, to address the EPA's September 11, 2006 comments on the 2006 RACT SIP.

the AVAQMD must, at a minimum, adopt RACT-level controls for all sources covered by a CTG document and for all major non-CTG sources of VOCs or NO_x within the nonattainment area. Any stationary source that emits or has the potential to emit at least 100 tons per year of VOCs or NO_x is a major stationary source in a moderate ozone nonattainment area (CAA section 182(b)(2), (f) and 302(j)), and any stationary source that emits or has the potential to emit at least 25 tons per year of VOCs or NO_x is a major stationary source in a severe ozone nonattainment area (CAA sections 182(d) and (f)).

Section IV.G of the preamble to the EPA's final rule to implement the 1997 8-hour ozone NAAQS (70 FR 71612, November 29, 2005) discusses RACT requirements. It states in part that where a RACT SIP is required, states implementing the 8-hour standard generally must assure that RACT is met, either through a certification that previously required RACT controls still represent RACT for 8-hour implementation purposes or through a new RACT determination. Section III.D of the preamble to the EPA's final rule to implement the 2008 ozone NAAQS (80 FR 12264, March 6, 2015) discusses similar requirements for RACT. The submitted documents provide AVAQMD's analyses of its compliance with the CAA section 182 RACT requirements for the 1997 and 2008 8-hour ozone NAAQS. The EPA's technical support documents (TSDs)⁴

⁴ The docket for this proposed action (<https://www.regulations.gov/docket?D=EPA-R09-OAR-2016-0524>) contains three TSDs. Two supported our

¹ Letter from Bret Banks, Antelope Valley Air Quality Management District (AVAQMD) to Alexis Strauss, U.S. Environmental Protection Agency (EPA) and Richard Corey, California Air Resources Board (CARB), dated June 26, 2017. Letter from Karen Magliano, CARB, to Alexis Strauss, EPA, dated June 27, 2017.

² 81 FR 90754 (December 15, 2016).

have more information about the District's submissions and the EPA's evaluations thereof.

II. The EPA's Evaluation and Proposed Action

A. How is the EPA evaluating the submitted documents?

SIP rules must be enforceable (see CAA section 110(a)(2)), must not interfere with applicable requirements concerning attainment and reasonable further progress or other CAA requirements (see CAA section 110(l)), and must not modify certain SIP control requirements in nonattainment areas without ensuring equivalent or greater emissions reductions (see CAA section 193). Generally, SIP rules must require RACT for each category of sources covered by a CTG document as well as each major source of VOCs or NO_x in ozone nonattainment areas classified as moderate or above (see CAA section 182(b)(2)). The AVAQMMD regulates a severe ozone nonattainment area (see 40 CFR 81.305), so the District's rules must implement RACT.

States should also submit for SIP approval negative declarations for those source categories for which they are not adopting CTG-based regulations (because they have no sources above the CTG recommended threshold) regardless of whether such negative declarations were made for an earlier SIP.⁵ To do so, the submittal should provide reasonable assurance that no sources subject to the CTG requirements currently exist or are planned for the AVAQMMD.

Guidance and policy documents that we use to evaluate enforceability, rule stringency requirements and CAA section 182 RACT requirements for the applicable criteria pollutants include the following:

1. "Final Rule to Implement the 8-hour Ozone National Ambient Air Quality Standard—Phase 2": (70 FR 71612; November 29, 2005).

2. "State Implementation Plans; General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990," 57 FR 13498 (April 16, 1992); 57 FR 18070 (April 28, 1992).

3. "Issues Relating to VOC Regulation Cutpoints, Deficiencies, and

Deviations," EPA, May 25, 1988 (the Bluebook, revised January 11, 1990).

4. "Guidance Document for Correcting Common VOC & Other Rule Deficiencies," EPA Region 9, August 21, 2001 (the Little Bluebook).

5. "State Implementation Plans; Nitrogen Oxides Supplement to the General Preamble; Clean Air Act Amendments of 1990 Implementation of Title I; Proposed Rule," (the NO_x Supplement), 57 FR 55620, November 25, 1992.

6. Memorandum from William T. Harnett to Regional Air Division Directors, (May 18, 2006), "RACT Qs & As—Reasonably Available Control Technology (RACT) Questions and Answers."

7. RACT SIPs, Letter dated March 9, 2006 from EPA Region IX (Andrew Steckel) to CARB (Kurt Karperos) describing Region IX's understanding of what constitutes a minimally acceptable RACT SIP.

8. RACT SIPs, Letter dated April 4, 2006 from EPA Region IX (Andrew Steckel) to CARB (Kurt Karperos) listing EPA's current CTGs, ACTs, and other documents which may help to establish RACT.

9. "Implementation of the 2008 National Ambient Air Quality Standards for Ozone: State Implementation Plan Requirements" (80 FR 12264; March 6, 2015).

With respect to major stationary sources, because the Antelope Valley ozone nonattainment area was classified as "moderate" nonattainment for the 1997 8-hour ozone NAAQS at the time that California submitted the 2006 RACT SIP to the EPA, the EPA evaluated this submission in accordance with the 100 ton per year (tpy) threshold for "major stationary sources" of VOC or NO_x emissions in moderate ozone nonattainment areas. (see CAA sections 182(b)(2) and (f)).

AVAQMMD's 2015 RACT SIP submittal contains the District's RACT evaluation for major stationary sources in accordance with the 25 tpy threshold for major stationary sources of VOC or NO_x emissions in severe ozone nonattainment areas. (see CAA sections 182(d) and (f)). The EPA also evaluated AVAQMMD's submittals for compliance with the additional RACT requirements that became applicable following the EPA's reclassification of the Antelope Valley ozone nonattainment area from "moderate" to "severe" nonattainment for the 1997 8-hour ozone NAAQS and classification as a severe ozone nonattainment area for the 2008 8-hour ozone NAAQS.

B. Do the documents meet the evaluation criteria?

Our December 15, 2016 proposed partial approval and partial disapproval rulemaking and associated TSDs provide an extensive evaluation of AVAQMMD's 2006 and 2015 RACT SIPs and negative declarations.⁶ See 81 FR 90754. The December 15 proposal found that the District's submissions largely demonstrate that the District's SIP meets the CAA section 182 RACT requirements, with the exception of four deficient rules, and nine missing negative declarations covering seven different CTG source categories. See *id.* at 90757; 42 U.S.C. 7511a. Accordingly, we proposed a partial approval of the District's 2006 and 2015 RACT SIPs, with the exception of the RACT demonstration for these four rules and seven CTG source categories.

Our analysis of the portion of the rule for which we proposed a partial approval remains unchanged, and we again propose to find that this portion of the District's submissions are consistent with CAA requirements and relevant guidance regarding enforceability, RACT, and SIP revisions. However, in light of the newly submitted AVAQMMD Federal Negative Declarations for Seven Control Techniques Guidelines Source Categories, and the District's commitment to adopt specific enforceable measures to remedy the identified rule deficiencies, the EPA is now updating its analysis of the previously-identified deficiencies.

The December 15, 2016 proposal concludes that with the exception of the following rules, all of the identified SIP rules implement RACT for the applicable CTG categories and for the major non-CTG stationary sources of VOC and NO_x for the 1997 and 2008 8-hour ozone NAAQS: Rule 462, *Organic Liquid Loading*; Rule 1110.2, *Emissions from Stationary, Non-road & Portable Internal Combustion Engines*; Rule 1151, *Motor Vehicle and Mobile Equipment Coating Operations*; and Rule 1171, *Solvent Cleaning Operations*. See 81 FR at 90756. This analysis remains unchanged. However, on June 26, 2017, the District transmitted to CARB and the EPA a commitment to adopt new or revised rules that will resolve the identified rule deficiencies, and to transmit these rules to CARB within 11 months of the effective date of the EPA's final action on the District's

December 15, 2016 proposed action (81 FR 90754) on the 2006 and 2015 AVAQMMD RACT SIPs (2006 and 2015 RACT SIP TSDs), and are dated November 2016. Although we are withdrawing our December 15, 2016 proposed partial approval/disapproval, the 2006 and 2015 RACT SIP TSDs contain pertinent information and analysis that support our current action. The third TSD supports today's action, and is dated July 2017.

⁵ 57 FR 13498, 13512 (April 16, 1992).

⁶ With the exception of the December 20, 2016 AVAQMMD Federal Negative Declarations for Seven Control Techniques Guidelines Source Categories, which had not yet been approved and submitted to EPA.

2006 and 2015 RACT SIP submittals. On June 27, 2017, CARB committed to submit these four rules to the EPA no later than one year from the effective date of our final action.⁷ These letters commit the District to adopt specific enforceable measures to correct the rule deficiencies, commit the State to submit them to the EPA within a one year time frame, and are clear and enforceable.

Accordingly, we believe these commitment letters are consistent with CAA requirements regarding conditional approval for the 2006 and 2015 RACT SIPs with respect to these four rules.⁸ See CAA section 110(k)(4).

Where there are no existing sources covered by a particular CTG document, states may, in lieu of adopting RACT requirements for those sources, adopt negative declarations certifying that there are no such sources in the relevant nonattainment area. On October 23, 2015, CARB submitted for SIP inclusion AVAQMD's Federal Negative Declarations for Twenty Control Techniques Guidelines Source Categories. Our TSD for the 2015 RACT SIP, accompanying the December 15, 2016 proposal, contains the EPA's evaluation of this submission. It states that we searched CARB's emissions inventory database and verified that there do not appear to be facilities in the AVAQMD that might be subject to these CTGs. This analysis remains unchanged, and we believe these negative declarations are consistent with the relevant policy and guidance regarding RACT.

Our December 15, 2016 proposed action on AVAQMD's 2006 and 2015 RACT SIPs summarizes the District's analyses of its negative declarations where it had no sources subject to the applicable CTG with regard to either or both the 1997 and 2008 8-hour ozone standards.⁹ The District based its conclusion on a review of permit files, emissions inventory data, and other documentation.

Based on the EPA's analysis of the District's negative declarations, our December 15, 2016 proposed action suggested that the AVAQMD should adopt negative declarations for the following CTG source categories if it

concludes it has no sources covered by the CTGs: (for the 1997 8-hour ozone standard) EPA-450/2-78-032, *Control of Volatile Organic Emissions from Existing Stationary Sources—Volume VII: Factory Surface Coating of Flat Wood Paneling*; EPA-450/3-82-009, *Control of Volatile Organic Compound Emissions from Large Petroleum Dry Cleaners*; EPA-450/2-77-008, *Control of Volatile Organic Emissions from Existing Stationary Sources—Volume II: Surface Coating of Cans, Coils, Paper, Fabrics, Automobiles, and Light-Duty Trucks, can coating portion*; and (for the 2008 8-hour ozone standard) EPA-450/2-77-008, *Control of Volatile Organic Emissions from Existing Stationary Sources—Volume II: Surface Coating of Cans, Coils, Paper, Fabrics, Automobiles, and Light-Duty Trucks, can coating portion*; EPA-450/2-77-026, *Control of Hydrocarbons from Tank Truck Gasoline Loading Terminals*; EPA-450/7-77-032, *Control of Volatile Organic Emissions from Existing Stationary Sources—Volume III: Surface Coating of Metal Furniture*; EPA-450/2-78-032, *Control of Volatile Organic Emissions from Existing Stationary Sources—Volume VII: Factory Surface Coating of Flat Wood Paneling*; EPA-453/R-08-003, *Control Techniques Guidelines for Miscellaneous Metal and Plastic Parts Coatings, drum coating portion*; EPA 453/R-08-003, *Control Techniques Guidelines for Miscellaneous Metal and Plastic Parts Coatings, pleasure craft portion*. See 81 FR at 90757.

It its June 7, 2017 submittal, AVAQMD Federal Negative Declarations for Seven Control Techniques Guidelines Source Categories, the District certified that it examined its permit files, emissions inventory and other documentation and determined that there are no sources in the CTG source categories listed above.¹⁰ The District adopted the negative declarations on December 20, 2016 after reasonable notice and public comment.¹¹ We believe these negative declarations are consistent with the relevant policy and guidance regarding RACT. The TSD for today's action has more information on our evaluation.

Because the District has now submitted negative declarations for the CTG source categories found to be missing in our December 15, 2016 proposal, the EPA now proposes to find

that AVAQMD has submitted all necessary negative declarations to complete its RACT SIP analysis for the 1997 and 2008 8-hour ozone standards. Accordingly, the District's 2006 and 2015 RACT SIPs satisfy the CAA section 182 RACT requirements, with the exception of the four deficient rules identified above, which the District has committed to correct.

Our 2006 and 2015 RACT SIP TSDs, our December 15, 2016 proposal and our July 2017 RACT SIPs TSD have more information on our evaluation.

C. EPA Recommendations To Further Improve the RACT SIPs

The 2015 RACT SIP TSD describes recommendations if additional emission reductions are needed for the next time the local agency modifies its rules.

D. Public Comment and Proposed Action

If a portion of a plan revision meets all the applicable CAA requirements, section 110(k)(3) authorizes EPA to approve the plan revision in part. 42 U.S.C. 7410(k)(3). In addition, section 110(k)(4) authorizes the EPA to conditionally approve a plan revision based on a commitment by the state to adopt specific enforceable measures by a date certain but not later than one year after the effective date of the plan approval. 42 U.S.C. 7410(k)(4). In this instance, the enforceable measures that the State must submit are new or revised rules that correct the rule deficiencies identified above. On June 27, 2017, the State transmitted a commitment letter from the AVAQMD to adopt and submit rules or rule revisions to correct the deficiencies identified in Rule 462, *Organic Liquid Loading*; Rule 1110.2, *Emissions from Stationary, Non-road & Portable Internal Combustion Engines*; Rule 1151, *Motor Vehicle and Mobile Equipment Coating Operations*; and Rule 1171, *Solvent Cleaning Operations* within one year of the effective date of the EPA's final action on the District's RACT SIP submittals. If the AVAQMD fails to comply with this commitment, this conditional approval will convert to a disapproval and start an 18-month clock for sanctions under CAA section 179(a)(2) and a two-year clock for a federal implementation plan (FIP) under CAA section 110(c)(1).

As authorized in section 110(k)(3) and (4) of the Act, the EPA proposes to conditionally approve AVAQMD's 2006 and 2015 RACT SIPs with respect to Rule 462, *Organic Liquid Loading*; Rule 1110.2, *Emissions from Stationary, Non-road & Portable Internal Combustion Engines*; Rule 1151, *Motor Vehicle and*

⁷ Letter from Bret Banks, Antelope Valley Air Quality Management District (AVAQMD) to Alexis Strauss, U.S. Environmental Protection Agency (EPA) and Richard Corey, California Air Resources Board (CARB), dated June 26, 2017. Letter from Karen Magliano, CARB, to Alexis Strauss, EPA, dated June 27, 2017.

⁸ We note that the District has begun acting on its commitment. On June 20, 2017, the AVAQMD Governing Board adopted Rule 1151.1 Motor Vehicle Assembly Coating Operations, for submittal to EPA via CARB.

⁹ 81 FR 90754 at 90756–57 (December 15, 2016).

¹⁰ Antelope Valley Air Quality Management District Federal Negative Declaration (8-hour ozone Standards) for Seven Control Techniques Guideline Source categories, signed by Brad Poiriez, Executive Officer, October 19, 2016.

¹¹ See Resolution 16–04; Affidavit of Publication, October 14, 2016.

Mobile Equipment Coating Operations; and Rule 1171, *Solvent Cleaning Operations*. Simultaneously, EPA proposes to fully approve the remainder of the 2006 and 2015 RACT SIPs, and to fully approve AVAQM's negative declarations submitted on October 23, 2015 and June 7, 2017. We are simultaneously withdrawing our December 15, 2016 proposal to partially approve and partially disapprove AVAQM's 2006 and 2015 RACT SIPs because the AVAQM has committed to address the identified deficiencies within one year of the effective date of our final action for today's proposed rulemaking.

We will accept comments from the public on this proposal until August 28, 2017. If we take final action to approve the submitted documents, our final action will incorporate these documents into the federally-enforceable SIP.

III. Statutory and Executive Order Reviews

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

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104-4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and

- Does not provide the EPA with the discretionary authority to address disproportionate human health or environmental effects with practical, appropriate, and legally permissible methods under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

List of Subjects in 40 CFR Part 52

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

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

Dated: July 14, 2017.

Deborah Jordan,

Acting Regional Administrator, Region IX.

[FR Doc. 2017-15982 Filed 7-27-17; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R08-OAR-2017-0019; FRL-9965-37-Region 8]

Approval and Promulgation of Air Quality Implementation Plans; North Dakota; Revisions to Air Pollution Control Rules

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing approval of State Implementation Plan (SIP) revisions received from the State of North Dakota on January 28, 2013, and April 22, 2014. The revisions are to Article 33-15 "Air Pollution Control" rules of the North Dakota

Administrative Code. The revisions include amendments to add EPA Reference Method 22 to determine compliance with a visible emissions limit, add significance levels for PM_{2.5}, modify existing significance levels for NO₂ and SO₂ and remove the significance level for PM₁₀. This action is being taken under section 110 of the Clean Air Act (CAA).

DATES: Written comments must be received on or before August 28, 2017.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R08-OAR-2017-0019 at <http://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from www.regulations.gov. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT:

Jaslyn Dobrahner, Air Program, U.S. Environmental Protection Agency (EPA), Region 8, Mail Code 8P-AR, 1595 Wynkoop Street, Denver, Colorado 80202-1129, (303) 312-6252, dobrahner.jaslyn@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

What should I consider as I prepare my comments for EPA?

1. *Submitting Confidential Business Information (CBI).* Do not submit CBI to the EPA through <http://www.regulations.gov> or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on a disk or CD-ROM that you mail to the EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that

includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register**, date, and page number);
- Follow directions and organize your comments;
- Explain why you agree or disagree;
- Suggest alternatives and substitute language for your requested changes;
- Describe any assumptions and provide any technical information and/or data that you used;
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced;
- Provide specific examples to illustrate your concerns, and suggest alternatives;
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats; and
- Make sure to submit your comments by the comment period deadline identified.

II. Background

On January 28, 2013, the State of North Dakota submitted a SIP revision containing amendments to Article 33–15 Air Pollution Control rules. We approved some of these revisions on October 21, 2016 (81 FR 72716). The remaining amendments include the following: A new rule that would give the State authority to issue general permits, revisions to significance levels and a revision to the prevention of significant deterioration (PSD) rules. This action addresses the revisions to significance levels. We will address the new general permit rule and the revision to the PSD rules in a separate action. The North Dakota State Health Council adopted the amendments on August 14, 2012 (effective January 1, 2013).

On April 22, 2014, the State of North Dakota submitted a SIP revision containing amendments to Article 33–15 Air Pollution Control rules. We approved some of these revisions on October 21, 2016 (81 FR 72716). The remaining amendment adds EPA Reference Method 22 for determining opacity for limits expressed as zero percent opacity. The North Dakota State Health Council adopted the

amendments on February 11, 2014 (effective April 1, 2014).

III. EPA's Review of the State of North Dakota's January 28, 2013 and April 22, 2014 Submittals

We evaluated North Dakota's January 28, 2013, and April 22, 2014 submittals regarding revisions to the State's Air Pollution Control rules as described in section II. We propose to approve all of the revisions under consideration in this proposed rulemaking.

A. January 28, 2013 SIP Submittal

We propose to approve PM_{2.5} concentration levels (0.3 µg/m³ annual and 1.2 µg/m³ 24-hour averaging time) the State added to 33–15–14–02.5.a in their January 2013 submittal. These PM_{2.5} values are the same as those in 40 CFR 51.165(b)(2) and are used in the same manner, *i.e.*, a source “will be considered to cause or contribute to a violation of an ambient air quality standard” when such source “would, at a minimum, exceed the [listed] significance levels at any locality that does not or would not meet the applicable ambient standard.” We also propose to approve revised significance levels for SO₂ and NO₂ (one-hour averaging time) contained in the State's January 2013 revisions to 33–15–14–02.5.a (SO₂ one-hour significance level revised from 25 to 7.8 µg/m³ and NO₂ one-hour significance level revised from 25 to 7.5 µg/m³). These revised SO₂ and NO₂ one-hour significance levels, although not listed in 40 CFR 51.165(b)(2), are consistent with our recommendations in guidance documents^{1,2} and strengthen the SIP. We note that the state regulation does not provide that a source with an impact below any of these significance levels is deemed to have demonstrated that it does not cause or contribute to a violation of the NAAQS. Thus, the rules that the EPA proposes to approve do not have an effect like those in 40 CFR 51.166(k)(2) and 52.21(k)(2) that were vacated and remanded by the U.S. Circuit Court of Appeals (*Sierra Club v. EPA*, 705 F.3d 458, 466 (D.C. Cir. 2013)).

Our proposed approval of the revisions to the State's significance levels at 33–15–14–02.5.a extends only to the use of these significance levels for the purpose stated in 40 CFR

¹ U.S. EPA Memo, *General Guidance for Implementing the 1-hour SO₂ National Ambient Air Quality Standard in Prevention of Significant Deterioration Permits, Including an Interim 1-hour SO₂ Significant Impact Level*, August 23, 2010.

² U.S. EPA Memo, *General Guidance for Implementing the 1-hour NO₂ National Ambient Air Quality Standard in Prevention of Significant Deterioration Permits, Including an Interim 1-hour NO₂ Significant Impact Level*, June 28, 2010.

51.165(b)(2). That is to determine that a major source or major modification will be considered to cause or contribute to a violation of a NAAQS when such source or modification would, at a minimum, exceed a significance level at any locality that does not or would not meet the applicable national standard.

In this same section, the State also removed the annual PM₁₀ significance level in 33–15–14–02.5.a. The annual PM₁₀ NAAQS was revoked in 2006 (71 FR 61144). North Dakota does not currently have any nonattainment areas for the annual PM₁₀ NAAQS. Thus, we propose to approve this revision.

B. April 22, 2014 SIP Submittal

The State's April 22, 2014 SIP submittal explains that the State added the EPA Reference Method 22 to the SIP,³ which the State will use to determine compliance with a visible emissions limit specified in a permit issued as zero percent opacity except for a certain frequency.

In 33–15–03–05, *Method of Measurement*, the State added EPA Reference Method 22 of Appendix A (“Visual Determination of Fugitive Emissions from Material Sources and Smoke Emissions from Flares”) adopted by reference in chapter 33–15–12, *Standards of Performance for New Stationary Sources*. This test method is used to determine the frequency of fugitive emissions from stationary sources and the frequency of visible smoke emissions from flares. Chapter 33–15–12 of the State's rules incorporates by reference 40 CFR part 60, appendix A, *Test Methods* as of July 1, 2015. The State's new rule specifies that Method 22 is applicable when “a visible emission limit is specified in a permit issued in accordance with this article as zero percent opacity except for certain frequency”. 33–15–03–05.2. The “frequency” of fugitive emissions refers to the length of time that fugitive emissions will be visible over a specified time interval (*i.e.*, one minute every 30 minutes, five minutes in two hours, etc.). Thus, a permit may specify zero percent opacity except for a certain frequency or length of time fugitive emissions may be observed over a specified time interval. The State's SIP rule does not make any substantive changes to Method 22, it merely incorporates the method into the SIP and allows it to be used to demonstrate compliance for sources that are subject to Article 15, “Air Pollution Control Rules.” We propose to approve of the State's incorporation of Method 22 from

³ State of North Dakota SIP Submittal Package (April 22, 2014), at PDF page 10.

40 CFR part 60, appendix A into the SIP because this allows for use of an EPA test method when specified in a permit issued in Article 15. Method 22 can be used for a variety of purposes, including determination of fugitive (non-stack) emissions and visible emissions from stationary sources (stacks) depending on the applicable emission standards⁴ and State permit requirements.

IV. What action is the EPA taking?

For the reasons expressed in III.A and III.B, the EPA is proposing to approve the following revisions, shown in Table 1, to the State's Air Pollution Control rules.

TABLE 1—LIST OF NORTH DAKOTA REVISIONS THAT THE EPA IS PROPOSING TO APPROVE

Revised sections in January 28, 2013 and April 22, 2014 submissions proposed for approval	
January 28, 2013 submittal:	33–15–14–02.5.a
April 22, 2014 submittal:	33–15–03–05.2

V. Incorporation by Reference

In this rule, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference North Dakota Administrative Code as described in section IV. of this preamble. The EPA has made, and will continue to make, these materials generally available through www.regulations.gov and/or at the EPA Region 8 Office (please contact the person identified in the “For Further Information Contact” section of this preamble for more information).

VI. Statutory and Executive Orders Review

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

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

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 76249, November 9, 2000).

List of Subjects in 40 CFR Part 52

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

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

Dated: July 13, 2017.

Debra H. Thomas,

Acting Regional Administrator, Region 8.

[FR Doc. 2017–15978 Filed 7–27–17; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS–2394–P]

RIN 0938–AS63

Medicaid Program; State Disproportionate Share Hospital Allotment Reductions

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: The Affordable Care Act requires aggregate reductions to state Medicaid Disproportionate Share Hospital (DSH) allotments annually beginning with fiscal year (FY) 2018. This proposed rule delineates a methodology to implement the annual allotment reductions.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on August 28, 2017.

ADDRESSES: In commenting, please refer to file code CMS–2394–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2394–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2394–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

⁴ U.S. EPA Question and Answer Document. *EPA Method 22—Visual Determination of Fugitive Emissions.* <https://www3.epa.gov/ttn/atw/area/method22qa.doc>.

[*Note:* This zip code for express mail or courier delivery only. This zip code specifies the agency's physical location.]

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850. [*Note:* This zip code for express mail or courier delivery only. This zip code specifies the agency's physical location.]

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Stuart Goldstein, (410) 786–0694 and Richard Cuno, (410) 786–1111.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication

of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Executive Summary

A. Purpose

Section 2551 of the Affordable Care Act amended section 1923(f) of the Social Security Act (the Act) by setting forth aggregate reductions to state Medicaid disproportionate share hospital (DSH) allotments annually from fiscal year (FY) 2014 through FY 2020. Subsequent legislation delayed the start of these reductions until FY 2018. These reductions will run through FY 2025. This proposed rule delineates the DSH Health Reform Methodology (DHRM) to implement annual Medicaid allotment reductions identified in the statute. This rule proposes a DHRM that accounts for relevant data that was unavailable to CMS during prior rulemaking for DSH allotment reductions originally set to take place for FY 2014 and FY 2015.

B. Summary of the Major Provisions

The statute as amended by the Affordable Care Act directs the Secretary to implement the annual DSH allotment reductions using a DHRM. This rule proposes to amend 42 CFR part 447 by establishing the DHRM, which incorporates factors identified in the statute.

C. Impacts

Taking the statutorily specified factors into account for each state, the proposed DHRM would generate a state-specific DSH allotment reduction amount for each fiscal year specified in statute. The total of all DSH allotment reduction amounts in a specific year would equal the aggregate annual reduction amount identified in statute for that same year. To determine the effective annual DSH allotment for each state, the state-specific annual DSH allotment reduction amount would be applied to the unreduced DSH allotment amount for its respective state.

II. Background

A. Introduction

In anticipation of lower uninsured rates and lower levels of hospital uncompensated care, the Affordable Care Act modified the amounts of funding available to states under the Medicaid program to address the situation of hospitals that serve a disproportionate share of low income

patients and therefore may have uncompensated care costs. Under sections 1902(a)(13)(A)(iv) and 1923 of the Act, states are required to make payments to qualifying “disproportionate share” hospitals (DSH payments). Section 2551 of the Affordable Care Act amended section 1923(f) of the Act, by adding paragraph (7), to provide for aggregate reductions in federal funding under the Medicaid program for such DSH payments for the 50 states and the District of Columbia. DSH allotments are not provided for the five U.S. territories.

Section 1923(f)(7)(A)(i) of the Act requires that the Secretary of Health and Human Services (the Secretary) implement the aggregate reductions in federal funding for DSH payments through reductions in annual state allotments of federal funding for DSH payments (state DSH allotments), and accompanying reductions in payments to each state. Since 1998, the amount of federal funding for DSH payments for each state has been limited to an annual state DSH allotment in accordance with section 1923(f) of the Act. The addition of section 1923(f)(7) of the Act requires the use of a DHRM to determine the percentage reduction in annual state DSH allotments to achieve the required aggregate annual reduction in federal DSH funding. The statutory reductions apply to all states and the District of Columbia except the State of Tennessee. Under section 1923(f)(6)(A)(vi) of the Act, notwithstanding any other provision of subsection 1923(f), or any other provision of law, the DSH allotment for Tennessee is established at \$53.1 million per year for FY 2015 through FY 2025. Therefore, Tennessee's DSH allotment is not subject to reduction under section 1923(f)(7) of the Act. For purposes of this rule, references to the reduction for “each state” means “each state subject to a DSH allotment reduction” (the 50 states and the District of Columbia, except Tennessee).

Section 1923(f)(7)(B) of the Act establishes the following factors that must be considered in the development of the DHRM. The methodology must:

- Impose a smaller percentage reduction on low DSH States;
- Impose the largest percentage reductions on:

++ States that have the lowest percentages of uninsured individuals during the most recent year for which such data are available;

++ States that do not target their DSH payments on hospitals with high volumes of Medicaid inpatients;

++ States that do not target their DSH payments on hospitals with high levels of uncompensated care; and

- Take into account the extent to which the DSH allotment for a state was included in the budget neutrality calculation for a coverage expansion approved under section 1115 as of July 31, 2009.

We describe in section II.B. of this proposed rule, the principles we intend to apply when calculating the annual DSH allotment reduction amounts for each state through the DHRM.

B. Legislative History and Overview

The Omnibus Budget Reconciliation Act of 1981 (OBRA '81) (Pub. L. 97–35, enacted on August 13, 1981) amended section 1902(a)(13) of the Act to require that Medicaid payment rates for hospitals take into account the situation of hospitals that serve a disproportionate share of low-income patients with special needs. Over the more than 35 years since this requirement was first enacted, the Congress has set forth in section 1923 of the Act payment targets and limits to implement the requirement and to ensure greater oversight, transparency, and targeting of funding to hospitals.

To qualify as a DSH under section 1923(b) of the Act, a hospital must meet two minimum qualifying criteria in section 1923(d) of the Act. The first criterion is that the hospital has at least two obstetricians who have staff privileges at the hospital and who have agreed to provide obstetric services to Medicaid individuals. This criterion does not apply to hospitals in which the inpatients are predominantly individuals under 18 years of age or hospitals that do not offer nonemergency obstetric services to the general public as of December 22, 1987. The second criterion is that the hospital has a Medicaid inpatient utilization rate (MIUR) of at least 1 percent.

Under section 1923(b) of the Act, a hospital meeting the minimum qualifying criteria in section 1923(d) of the Act is deemed as a DSH if the hospital's MIUR is at least one standard deviation above the mean MIUR in the state for hospitals receiving Medicaid payments, or if the hospital's low-income utilization rate exceeds 25 percent. States have the option to define DSHs under the state plan using alternative qualifying criteria as long as the qualifying methodology comports with the deeming requirements of section 1923(b) of the Act. Subject to certain federal payment limits, states are afforded flexibility in setting DSH state plan payment methodologies to the extent that these methodologies are

consistent with section 1923(c) of the Act.

Section 1923(f) of the Act limits federal financial participation (FFP) for total statewide DSH payments made to eligible hospitals in each federal FY to the amount specified in an annual DSH allotment for each state. Although there have been some special rules for calculating DSH allotments for particular years or sets of years, section 1923(f)(3) of the Act establishes a general rule that state DSH allotments are calculated on an annual basis in an amount equal to the DSH allotment for the preceding FY increased by the percentage change in the consumer price index for all urban consumers for the previous FY. The annual allotment, after the consumer price index increase, is limited to the greater of the DSH allotment for the previous year or 12 percent of the total amount of Medicaid expenditures under the state plan during the FY. Allotment amounts were originally established in the Medicaid Voluntary Contribution and Provider Specific Tax Amendments of 1991 based on each state's historical DSH spending.

Section 1923(g) of the Act also limits DSH payments by imposing a hospital-specific limit on DSH payments. Specifically, a DSH payment must not exceed a hospital's uncompensated care costs for that year (*i.e.* it must not exceed the costs of providing inpatient hospital and outpatient hospital services to Medicaid patients and the uninsured, minus payments received by the hospital by or on the behalf of those patients). FFP is not available for DSH payments that exceed the hospital-specific limit.

The statute, as amended by the Affordable Care Act, required annual aggregate reductions in federal DSH funding from FY 2014 through FY 2020. However, subsequent legislation extended the reductions, modified the amount of the reductions, and delayed the start of the reductions until FY 2018. The most recent related amendments to the statute were through the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted April 16, 2015). Currently, the aggregate annual reduction amounts set to begin in FY 2018 are specified in section 1923(f)(7)(A)(ii) of the Act:

- \$2,000,000,000 for FY 2018.
- \$3,000,000,000 for FY 2019.
- \$4,000,000,000 for FY 2020.
- \$5,000,000,000 for FY 2021.
- \$6,000,000,000 for FY 2022.
- \$7,000,000,000 for FY 2023.
- \$8,000,000,000 for FY 2024.
- \$8,000,000,000 for FY 2025.

To implement these annual reductions, the statute requires that the Secretary reduce annual state DSH allotments, and payments to states, based on a DHRM specified in section 1923(f)(7)(B) of the Act. The proposed DHRM relies on statutorily identified factors collectively to determine a state-specific DSH allotment reduction amount to be applied to the allotment that is calculated under section 1923(f) of the Act prior to the reductions under section 1923(f)(7) of the Act.

In the May 15, 2013 **Federal Register** (78 FR 28551), we published the “Medicaid Program; State Disproportionate Share Hospital Allotment Reductions” proposed rule. The rule proposed a DHRM that relied on the statutory factors and solicited comments regarding whether state decisions to extend Medicaid coverage to low-income adults under section 1902(a)(10)(A)(i)(VIII) of the Act should be accounted for in the reduction methodology. We received several comments in support of accounting for Medicaid coverage expansion and numerous comments in opposition.

In the September 18, 2013 **Federal Register** (78 FR 57293), we published the “Medicaid Program; State Disproportionate Share Hospital Allotment Reductions” final rule (herein referred to as the “2013 DSH allotment reduction final rule”). In the 2013 DSH allotment reduction final rule, we decided to finalize a DHRM that would be in place only for FY 2014 and FY 2015 to allow time for reevaluation of the methodology with improved and more recent data and information about the impact of the Affordable Care Act on levels of coverage and uncompensated care. As a result of our reevaluation, we are now proposing to modify the DHRM factor weights and to use improved data sources where possible, as discussed in this proposed rule.

C. DHRM Data Sources

The statute establishes parameters regarding data and data sources for specific factors in the development of the DHRM. We are proposing to utilize for the DHRM, wherever possible, data sources and metrics that are consistent with the statute, transparent, and readily available to CMS, states, and the public, such as: DSH Medicaid Inpatient Utilization Rate (MIUR) data; Medicaid DSH data reported as required by section 1923(j) of the Act; United States Census Bureau data; existing state DSH allotments; and Form CMS–64 Medicaid Budget and Expenditure System (MBES) data. We are proposing to utilize the most recent year available for all data

sources and are proposing to align data sources whenever possible. Selected data sources are discussed in greater detail below.

1. MIUR Data

To ensure that all hospitals are properly deemed disproportionate share in accordance with section 1923(b) of the Act, states must determine the mean MIUR for hospitals receiving Medicaid payments in the state and the value of one standard deviation above the mean. States are currently required to provide this data to CMS annually under § 447.294(d) (CMS–R–266, Office of Management and Budget (OMB) 0938–0746). We will utilize MIUR data from the year that corresponds to the DSH audit SPRY used in the calculation of each state's DSH allotment reductions.

2. Medicaid DSH Audit and Reporting Data

We are also proposing to rely on data derived from Medicaid DSH audit (CMS–R–266, OMB 0938–0746) and reporting data (CMS–R–266, OMB 0938–0746). The data is reported by states as required by section 1923(j) of the Act and the “Medicaid Disproportionate Share Hospital Payments” final rule published on December 19, 2008 (73 FR 77904) (and herein referred to as the 2008 DSH audit final rule) requiring state reports and audits to ensure the appropriate use of Medicaid DSH payments and compliance with the hospital-specific DSH limit imposed at section 1923(g) of the Act. This is the only comprehensive data source for DSH hospitals that identifies hospital-specific DSH payments and uncompensated care costs in a manner consistent with Medicaid DSH program requirements.¹

To date, we have received rich, comprehensive audit and reporting data from each state that makes Medicaid DSH payments. To facilitate the provision of high quality data, we provided explicit parameters in the 2008 DSH audit final rule and associated policy guidance for calculating and reporting data elements. As the data elements are based on hospital costs reports and are subject to audit, the data elements are not due to CMS until the end of the calendar year 3 years following the end of each state plan rate year (SPRY). Additionally, state submitted audit and reporting data

is subject to detailed CMS review to ensure quality and accuracy and requires significant resources to compile and prepare for use in the proposed DHRM. This means that the data used for the methodology may not be the most recently submitted data, but instead the most recent data available to us in usable form. For FY 2018 we anticipate utilizing SPRY 2013 DSH audit and reporting data, which was due from states to CMS on December 31, 2016. We considered utilizing alternative uncompensated cost data and Medicaid utilization data from sources such as the Medicare Form CMS–2552 (OMB 0938–0050). The DSH audit and reporting data, however, remains the only comprehensive reported data available that is consistent with Medicaid program requirements.

3. United States Census Bureau Data

As required by the statute, the DHRM must impose the largest percentage DSH allotment reductions on the states that have the lowest percentages of uninsured individuals. Although other sources of this information could be considered for this purpose, the statute explicitly refers to the use of data from the Census Bureau for determining the percentage of uninsured for each state. As with the 2013 DSH allotment reduction final rule, we identified and considered two Census Bureau data sources for this purpose: The American Community Survey (ACS); and the Annual Social and Economic Supplement to the Current Population Survey (CPS). In consultation with the Census Bureau, we are proposing to use the data from the ACS for the following reasons. First, the ACS is the largest household survey in the United States; in that regard, the annual sample size for the ACS is over 30 times larger than that for the CPS—about 3 million for the ACS versus 100 thousand for the CPS. The ACS is conducted continuously each month throughout the year, with the sample for each month being roughly $\frac{1}{12}$ th of the annual total, while the CPS is conducted in the first 4 months following the end of the survey year.

Finally, although the definition of uninsured and insured status is the same for the ACS and the CPS, the CPS considers the respondents as uninsured if they are uninsured at any time during the year whereas the ACS makes this determination based on whether the respondent has coverage at the time of the interview, which are conducted at various times throughout the year. For these reasons, and with the recommendation of the Census Bureau, we determined that the ACS is the

appropriate source for establishing the percentage of uninsured for each state for purpose of the proposed DHRM.

III. Provisions of the Proposed Rule

This proposed rule proposes to amend 42 CFR 447.294 by establishing the DHRM for FY 2018 and subsequent fiscal years, which incorporates factors identified in the statute. We are proposing in § 447.294(a) and (e) to remove language referring to specific federal fiscal years (FY 2014 and FY 2015) when calculating state annual DSH allotment reductions.

We are proposing in § 447.294(b) to add the definition of “Total hospital cost.”

We are proposing in § 447.294(d) to clarify state data submission requirements by simplifying the language and removing language related to the submission of data for previous state plan rate years (SPRY) already provided to CMS.

We are also proposing to revise § 447.294(e)(3)(i) to clarify that the total Medicaid service expenditures used in the calculation of the Low DSH adjustment factor (LDF) must be for the applicable year. We are proposing to revise § 447.294(e)(5)(i) through (iii) to adjust the weighting of statutorily defined factors.

In addition, we are proposing in § 447.294(f) to update the paragraph to remove references to specific fiscal years.

A. DHRM Overview

The statute requires aggregate annual reduction amounts to be implemented through a DHRM designed by the Secretary consistent with statutorily-established factors. Taking these factors into account for each state, the proposed DHRM would generate a state-specific DSH allotment reduction amount for the specified fiscal years for all states and the District of Columbia with the exception of Tennessee whose DSH allotment is defined in section 1923(f)(6)(A)(vi) of the Act to be \$53.1 million, notwithstanding DSH allotment reductions in section 1923(f)(7), for each FY from 2015 through 2025. The total of all DSH allotment reduction amounts would equal the aggregate annual reduction amounts identified in statute for each fiscal year. To determine the effective annual DSH allotment for each state, the state-specific annual DSH allotment reduction amount would be applied to the unreduced DSH allotment amount for its respective state.

We would calculate an unreduced DSH allotment for each state prior to the beginning of each FY, as we do currently. This unreduced allotment is

¹ CMS published a final rule on April 3, 2017 (82 FR 16114) revising the text of 42 CFR 447.299(c)(1). Effective June 2, 2017, the rule amended paragraph (c)(1) to clarify that uncompensated care costs are calculated using total cost of care for Medicaid inpatient and outpatient services, net of third-party payments.

determined by calculating the allotment in section 1923(f) of the Act prior to the application of the DHRM under section 1923(f)(7) of the Act. The unreduced allotment would serve as the base amount for each state to which the state-specific DSH allotment reduction amount would apply annually. In this proposed rule, we are utilizing estimated unreduced DSH allotments for FY 2017 for illustrative purposes. Please note that this illustrative estimate may rely on different data than what is proposed to be used when calculating annual DSH allotment reductions for FY 2018. Specifically, we anticipate that more recent data will be available when calculating the final allotment reductions. For purposes of this illustrative example, we have utilized the most recent available data to CMS.

We propose to apply the DHRM to the unreduced DSH allotment amount on an annual basis for the fiscal years specified in statute. Under the DHRM, we consider the factors identified in the statute to determine each state's annual state-specific DSH allotment reduction amount.

The proposed DHRM utilizes the best available data at the time of calculation and would not recalculate reductions based on revised or late DSH audit reports, MIUR data, or other relevant data. The DHRM would also rely on a series of interacting calculations that result in the identification of state-specific reduction amounts that, when summed, equal the aggregate DSH allotment reduction amount identified by the statute for each applicable year. The proposed DHRM accomplishes this through the following summarized steps:

(1) Separate states into two overall groups, non-low DSH states and low DSH states, to give effect to the statutory low-DSH criterion. (States falling into each category are listed in Table 1.)

(2) Proportionately allocate aggregate DSH funding reductions to each of these two state groups based on each state group's proportion of the total national unreduced DSH allotment amount.

(3) Apply a low DSH adjustment percentage to adjust the non-low DSH and low DSH state groups' DSH funding reduction amount. This step maintains the combined aggregate DSH funding reduction for the low DSH and non-low DSH state groups by distributing a portion of the unadjusted low DSH state DSH funding reduction amount across the non-low DSH state group, as described in greater detail below.

(4) Divide each state group's DSH allotment reduction amount among three statutorily identified factors, the Uninsured Percentage Factor (UPF), the

High Level of Uncompensated Care Factor (HUF), and the High Volume of Medicaid Inpatients Factor (HMF). We are proposing to assign a 50 percent weight to the UPF and a 50 percent combined weight for the two DSH payment targeting factors (a 25 percent weight for the HUF, and a 25 percent weight for the HMF). This approach would assign equal weights based on the statutory structure under which the UPF is presented separately, in section 1923(f)(7)(B)(i)(I) of the Act, while the HMF and HUF are grouped together in section 1923(f)(7)(B)(i)(II) of the Act, at items (aa) and (bb). Additionally, compared to the approach taken in the 2013 DSH allotment reduction final rule, this weight assignment would place greater emphasis on the UPF to:

- Reduce the impact of the DSH allotment reduction for states with greater DSH need due to high uninsurance rates.
- Give greater weight to more recent data, since the UPF data relies on more recent data than the HUF and HMF.

We considered various alternative weight assignments prior to proposing equal weights to the requirement at section 1923(f)(7)(B)(i)(I) of the Act and to the combined requirements at section 1923(f)(7)(B)(i)(II) of the Act. We have decided upon the 50 percent weight to the UPF and a 50 percent combined weight for the two DSH payment targeting factors in order to reduce the impact of the DSH allotment reductions for states with high uninsurance rates, place a greater weight to more recent data, and reflect how these factors are specified in statute.

(5) Limit the reduction to be applied to each state's total unreduced DSH allotment to 90 percent of its original unreduced allotment. Any excess reduction amounts called for under the DHRM which are limited by this reduction cap will be factored back into the reduction model and be redistributed among the remaining states that do not exceed the reduction cap based on the proportion of each remaining state's allotment reduction amount to the aggregate allotment reduction amount for its respective state group. This operation would be performed separately for each state group such that, for example, an excess reduction amount attributable to a low DSH state would be reapportioned only among other low DSH states and would not be reapportioned among any states in the non-low DSH state group. By limiting the overall amount by which each state's allotment may be decreased, we propose to preserve at least 10 percent of each state's unreduced DSH allotment, thereby allowing all states to

continue to making DSH payments. Placing limits on the reductions applied to each state's original unreduced allotments is a new proposal that was not considered in the 2013 DSH allotment reduction final rule. In view of the then-required aggregate DSH allotment reduction amounts and the DHRM under the 2013 DSH allotment reduction final rule, no state was in jeopardy of having its entire DSH allotment eliminated for FY 2014 or FY 2015 at the time that rule was promulgated. However, with the larger reduction amounts currently scheduled for FYs 2018 through 2025 under the statute, which are as high as \$8 billion annually, states may experience the elimination of their entire DSH allotment without the inclusion of a reduction cap methodology in the DHRM. As such, we are soliciting comments on alternative methodologies that would limit the allotment reduction amount that states may receive through the DHRM, specifically on how excess reduction amounts are factored back into the reduction model and on what to use as the maximum reduction percentage. Although we did consider different reduction cap percentages, we believe the proposed 10 percent reduction cap strikes a balance between ensuring reduction amounts are determined based on the statutory DHRM factors and ensuring states maintain the ability to make [an appreciable amount of] DSH payments. Higher reduction caps would cause the reductions to be evenly distributed among all states, instead of being based on the statutory DHRM factors. No cap might result in the complete elimination of some states' DSH allotments and lower caps might result in states with an insignificant amount of DSH allotment with which to make DSH payments.

(6) For each state group, determine state-specific DSH allotment reduction amounts relating to the UPF. To accomplish this, we will compare each state's uninsurance rate to the uninsurance rates of all states in relation to each state's unreduced allotment in proportion to its respective state group's total allotment in order to calculate each state's reduction. As required by statute, states with *lowest* uninsurance rates will receive *largest* percentage DSH reductions.

(7) For each state group, determine state-specific DSH allotment reduction amounts relating to the HUF. By utilizing the most recently available Medicaid DSH audit and reporting data, we will determine the mean uncompensated care level for each state in order to determine the total payments each state makes to non-high

uncompensated care level hospitals. We will then determine the HUF by dividing the total of each state's total payments made to non-high uncompensated care level hospitals by the total payments made non-high uncompensated care level hospitals for its respective state group.

(8) For each state group, determine state-specific DSH allotment reduction amounts relating to the HMF. Again, by utilizing the most recently available Medicaid DSH audit and reporting data, we will determine the mean MIUR for each state in order to determine the amount of DSH payments each state makes to non-high Medicaid volume hospitals. We will then determine the HMF by dividing each state's total payments made to non-high volume Medicaid hospitals by the total payments made non-high volume Medicaid hospitals for its respective state group.

(9) Apply a section 1115 Budget Neutrality Factor for each qualifying state. To apply this factor, we will not reduce any portion of a state's DSH allotment which was included in the budget neutrality calculation for a coverage expansion that was approved under section 1115 of the Act as of July 31, 2009. We will assign any qualifying states an average percentage reduction amount within its respective state group for diverted DSH allotment amounts that are not related to a coverage expansion in effect as of July 31, 2009 and for which the state does not have complete and/or relevant DSH payment data.

(10) Identify the state-specific DSH allotment reduction amount.

(11) Subtract each state's state-specific DSH allotment reduction amount from each state's unreduced DSH allotment to determine the state's available DSH allotment for the applicable year.

The manner in which each of the five factors are considered and calculated in the proposed DHRM is described in greater detail below.

The proposed DHRM recognizes the variations in DSH allotments among states and the application of the methodology generates a lesser impact on low DSH states. The DHRM is designed to determine DSH reductions in an equitable manner by grouping similar states into groups for purposes of applying the statutory reduction factors. Reductions assigned through the HMF and HUF would lessen the impact on states that have targeted DSH payments to hospitals that have high volumes of Medicaid inpatients and to hospitals that have high levels of uncompensated care, respectively, while incentivizing payment targeting

for future DSH payments. As specified in statute, the DHRM would also take into account the extent to which the DSH allotment for a state was included in part or in whole in the budget neutrality calculation for a coverage expansion approved under section 1115 of the Act as of July 31, 2009 by excluding from DSH allotment reduction the amount of DSH that qualifying states continue to divert specifically for coverage expansion in the budget neutrality calculation. Any amount of DSH diverted for other purposes under the demonstration would still be subject to reduction by automatically assigning qualifying states an average percentage reduction amount within its respective state group for factors for which the state does not have complete and/or relevant DSH payment data.

B. Low DSH Adjustment Factor (LDF)

Section 1923(f)(7)(B)(ii) of the Act requires the DHRM to impose a smaller percentage reduction on "low DSH states" that meet the criterion described in section 1923(f)(5)(B) of the Act. To qualify as a low DSH state, total expenditures under the state plan for DSH payments for FY 2000, as reported to us as of August 31, 2003, had to have been greater than zero but less than 3 percent of the state's total Medicaid state plan expenditures during the FY. Historically, low DSH states (identified in Table 1) have received lower DSH allotments relative to their total Medicaid expenditures than non-low DSH states.

To meet the statutory requirement to impose a smaller percentage reduction on low DSH states, the DHRM would create two state groups (low DSH states and non-low DSH states), then would apply the LDF when allocating reduction amounts to each state group. The LDF is calculated and applied as follows:

(1) Separate states into two groups, non-low DSH states and low DSH states.

(2) Divide each state's unreduced preliminary DSH allotment for the year for which the reduction is calculated by estimated Medicaid service expenditures for that same year. Currently, we create a preliminary DSH allotment based on the estimates available in August of the prior year and we issue a final DSH allotment once the federal FY ends.

(3) For each state group, calculate the non-weighted mean of the value calculated in step 2 for states in the group.

(4) Divide the average calculated in step 3 for the low DSH state group by

the average calculated in step 3 for the non-low DSH state group.

(5) Convert this number to a percentage. This percentage is the LDF.

(6) Multiply the proportionately allocated DSH funding reductions for the low-DSH state group by the LDF percentage to determine the aggregate DSH reduction amount that would be distributed across the low DSH state group.

(7) Subtract the aggregate DSH reduction amount determined in step 6 from the proportionately allocated DSH funding reduction for the low-DSH state group, and add the remainder to the aggregate DSH reduction amount that would be distributed across the non-low DSH state group.

We considered using various alternative proportional relationships to establish the LDF, including the proportion of each state group's annual Medicaid DSH expenditures to total Medicaid expenditures. However, we believe that this may benefit non-low DSH states that are unable to or otherwise do not spend their existing DSH allotment amount. Therefore, we are proposing to calculate the LDF based on the proportion of each state group's DSH allotments to total Medicaid expenditures.

C. Factor 2—Uninsured Percentage Factor (UPF)

The second factor considered in the proposed DHRM is the UPF identified at section 1923(f)(7)(B)(i)(I) of the Act, which requires that the DHRM impose the largest percentage DSH allotment reductions on states that have the lowest percentages of uninsured individuals. The statute also requires that the percentage of uninsured individuals is determined on the basis of data from the Census Bureau, audited hospital cost reports, and other information likely to yield accurate data, during the most recent year for which such data are available.

To determine the percentage of uninsured individuals in each state, the proposed DHRM relies on the total population and uninsured population as identified in the most recent "1-year estimates" data available from the ACS conducted by the Census Bureau. The Census Bureau generates ACS "1-year estimates" data annually based on a point-in-time survey of approximately 3 million individuals. For purposes of the proposed DHRM, we would utilize the most recent ACS data available at the time of the calculation of the annual DSH allotment reduction amounts.

The UPF, as applied through the proposed DHRM, has the effect of imposing the lowest relative DSH

allotment reductions on states that have the highest percentage of uninsured individuals. The UPF would mitigate the DSH reduction for states with the highest percentage of uninsured individuals.

The proposed UPF is determined separately for each state group as follows:

(1) *Uninsured Value*—Using United States Census Bureau data, calculate each state's uninsured value by dividing the total state population by the uninsured in the state. (This is different than the percentage rate of uninsurance; the rate of uninsurance can be obtained by dividing 100 by this number.)

(2) *Uninsured Allocation Component*—Determine the relative uninsured value for each state compared to other states in the state group by dividing the value in step one by the state group total of step one values. The result should be a percentage, and the total of the percentages for all states in the state group should total 100 percent.

(3) *Allocation Weighting Factor*—To ensure that larger and smaller states are given fair weight in the final UPF, divide each state's preliminary unreduced DSH allotment by the sum of all unreduced preliminary DSH allotments in the respective state group to obtain allocation weighting factor, expressed as a percentage. The sum of all weighting factors should equal 100 percent. Then, take this percentage for each state and multiply it by the state's uninsured allocation component determined in step 2. The result is the allocation weighting factor.

(4) *UPF*—For each state group, divide each state's allocation weighting factor by the sum of all allocation weighting factors. The resulting percentage is the UPF.

We would determine the UPF portion of the proposed aggregate DSH allotment reduction allocation for each state by multiplying the state's UPF by the aggregate DSH allotment reduction allocated to the UPF factor for the respective state group. As with the prior factor, we propose to utilize preliminary DSH allotment estimates to develop the DSH reduction factors.

D. Factor 3—High Volume of Medicaid Inpatients Factor (HMF)

The third factor considered in the proposed DHRM is the High Volume of Medicaid Inpatients Factor (HMF) identified at section 1923(f)(7)(B)(i)(II)(aa) of the Act, which requires that the DHRM impose the largest percentage DSH allotment reductions on states that do not target DSH payments to hospitals with high volumes of Medicaid inpatients. For

purposes of the DHRM, the statute defines hospitals with high volumes of Medicaid patients as those defined in section 1923(b)(1)(A) of the Act. These hospitals must meet minimum qualifying requirements at section 1923(d) of the Act and have an MIUR that is at least one standard deviation above the mean MIUR for hospitals receiving Medicaid payments in the state. Every hospital that meets that definition is deemed a disproportionate share hospital and is statutorily required to receive a DSH payment.

States that have been, and continue to, target a large percentage of their DSH payments to hospitals that are federally deemed as a DSH based on their MIUR would receive the lowest reduction amounts relative to their total spending. States that target the largest amounts of DSH payments to hospitals that are not federally deemed based on MIUR would receive the largest reduction amounts under this factor. The current DSH allotment amounts are unrelated to the amounts of MIUR-deemed hospitals and their DSH-eligible uncompensated care costs. By basing the HMF reduction on the amounts that states do not target to hospitals with high volumes of Medicaid inpatients as described below in section (4), this proposed methodology incentivizes states to target DSH payments to such hospitals.

To ensure that all deemed disproportionate share hospitals receive a required DSH payment, states are already required to determine the mean MIUR for hospitals receiving Medicaid payments in the state and the value of one standard deviation above the mean. This rule proposes to rely on MIUR information for use in the DHRM that CMS collects from states on an annual basis under § 447.294(d). When a state or states do not submit this required MIUR information timely, for purposes of this factor, we would assume that the state(s) have the highest value of one standard deviation above the mean reported among all other states that did submit this information timely.

The calculation of the HMF would rely on extant data that should be readily available to states. The following data elements are used in the proposed HMF calculation: The preliminary unreduced DSH allotment for each state; the DSH hospital payment amount reported for each DSH in accordance with § 447.299(c)(17); the MIUR for each DSH reported in accordance with § 447.299(c)(3); and the value of one standard deviation above the mean MIUR for hospitals receiving Medicaid payments in the state reported separately.

The proposed HMF is a state-specific percentage that would be calculated separately for each state group (low DSH and non-low DSH) as follows:

(1) For each state, classify each DSH that has an MIUR at least one standard deviation above the mean MIUR for hospitals receiving Medicaid payments in the state as a High Medicaid Volume hospital.

(2) For each state, determine the amount of DSH payments to non-High Medicaid Volume DSH hospitals. This data element should come from the most recently submitted and accepted DSH audit template.

(3) For each state, determine a percentage by dividing the state's total DSH payments made to non-High Medicaid Volume hospitals by the aggregate amount of DSH payments made to non-High Medicaid Volume hospitals for the entire state group. The result of step 3 is the HMF.

(4) Determine each state's HMF reduction amount by applying the HMF percentage to the aggregate reduction amount allocated to this factor for each state group.

As a result of this methodology, there are a number of interactions that may occur for states among DSH payment methodologies, DSH allotments, and DSH allotment reductions. Most of these scenarios work in concert with this factor's established reduction relationship. For example, if a state paid out its entire DSH allotment to hospitals with high volumes of Medicaid inpatients, it would receive no reduction associated with this factor because all DSH payments were made only to hospitals that qualify as high volume. The results of this scenario would be consistent with the methodology because the state is incentivized to target DSH payments to high Medicaid volume hospitals.

Another example is a state that makes DSH payments up to the hospital-specific DSH limit to all hospitals with high Medicaid volume but also uses its remaining allotment to make DSH payments to hospitals that do not qualify as high volume. In this example, the state would receive a reduction under this factor based on the amount of DSH payments it made to non-high Medicaid volume hospitals. Though the state targeted DSH payments to hospitals with high Medicaid volume, the existing size of its DSH allotment permitted it to make DSH payments to hospitals that did not meet the statutory definition of high Medicaid volume. In that situation, this allotment reduction would effectively reduce a state's existing DSH allotment to the extent that the allotment exceeded the

maximum amount that the state could pay to hospitals that are high Medicaid volume. The resulting HMF reduction would be greater for states with DSH allotments large enough to pay significant amounts to non-high Medicaid volume hospitals. This ensures that states target DSH payments to high Medicaid volume hospitals and distribute the reductions in such a way as to promote the ability of all states to provide DSH funds to high Medicaid volume hospitals.

We seek comments on the proposed DHRM with respect to whether the proposed implementation of this factor is expected to be effective in tying the level of DSH reductions to the targeting of DSH payments to high Medicaid volume hospitals.

E. Factor 4—High Level of Uncompensated Care Factor (HUF)

The fourth factor considered in the DHRM is the HUF identified at section 1923(f)(7)(B)(i)(II)(bb) of the Act, which requires that the DHRM impose the largest percentage DSH allotment reductions on states that do not target DSH payments to hospitals with high levels of uncompensated care. We are proposing to rely on the existing statutory definition of uncompensated care cost used in determining the hospital-specific limit on FFP for Medicaid DSH payments.

As defined in section 1923(g)(1) of the Act, the state must calculate for each hospital, for each FY, the difference between the costs incurred by that hospital for furnishing inpatient hospital and outpatient hospital services during the applicable state FY to Medicaid individuals and individuals who have no health insurance or other source of third party coverage for the inpatient hospital and outpatient hospital services they receive, less all applicable revenues received for these hospital services. This difference, if any, between incurred inpatient hospital and outpatient hospital costs and associated revenues is considered a hospital's uncompensated care costs, or hospital-specific DSH limit.

For purposes of this rule, we are proposing to rely on this definition of uncompensated care costs for the calculation of the HUF, as reported by states on the most recent available Medicaid DSH audit and reporting data. For the proposed DHRM, hospitals with high levels of uncompensated care costs are defined based on a comparison with other Medicaid DSH hospitals in their state. Any hospital that exceeds the mean ratio of uncompensated care costs to total Medicaid and uninsured inpatient and outpatient hospital service

costs within its state is considered a hospital with a high level of uncompensated care. This data is consistent with the existing Medicaid DSH program definition of uncompensated care and is readily available to states and CMS.

The following data elements would be used in the HUF calculation:

- The preliminary unreduced DSH allotment for each state;
- DSH hospital payment amounts reported for each DSH in accordance with § 447.299(c)(17);
- Uncompensated care cost amounts reported for each DSH in accordance with § 447.299(c)(16);
- Total Medicaid cost amounts reported for each DSH in accordance with § 447.299(c)(10); and
- Total uninsured cost amounts reported for each DSH in accordance with § 447.299(c)(14).
- Total hospital cost amounts reported for each DSH in accordance with § 447.299(c)(20).

The statute also requires that uncompensated care costs used in this factor of the DHRM exclude bad debt. The proposed rule relies on the uncompensated care cost data derived from Medicaid DSH audit and reporting required by section 1923(f) of the Act and implementing regulations. This uncompensated care data excludes bad debt, including unpaid co-pays and deductibles, associated with individuals with a source of third party coverage for the service received during the year.

The HUF is a state-specific percentage that is calculated separately for each state group (low DSH and non-low DSH) as follows:

(1) Determine each disproportionate share hospital's uncompensated care level by dividing its uncompensated care cost by total hospital cost. This data element would come from the most recently submitted and accepted Medicaid DSH audit and associated reporting.

(2) For each state, calculate the weighted mean uncompensated care level.

(3) Identify all hospitals that meet or exceed the mean uncompensated care level as high uncompensated care level hospitals. We are also considering identifying a metric higher than the mean for purposes of identifying hospitals as high uncompensated care level hospitals and are specifically soliciting comments on alternative methodologies.

(4) For each state, determine the total amount of DSH payments to non-high uncompensated care level hospitals.

(5) For each state, determine a percentage by dividing the state's total

DSH payments made to non-high uncompensated care level hospitals by the aggregate amount of DSH payments made to non-high uncompensated care level hospitals for the entire state group. The result would be the HUF.

(6) Determine each state's HUF reduction amount by applying the HUF percentage to the aggregate reduction amount allocated to this factor for each state group.

In previous rulemaking, we identified some potential scenarios where the interactions may have been inconsistent with the intent of this methodology. Under the 2013 DSH allotment reduction final rule, it was possible for a hospital not to have been considered to have a higher level of uncompensated care even though it provided a higher percentage of services to Medicaid and uninsured individuals and had greater total qualifying uncompensated care costs than another hospital that did qualify as having a high level of uncompensated care. This was due to the previous formula determining the level of uncompensated care by dividing uncompensated care by the sum of total Medicaid costs and total uninsured costs. We propose to resolve this problem discussed in earlier rulemaking by determining the level of uncompensated care by dividing uncompensated care costs by total hospital costs.

We seek comments on the proposed DHRM with respect to whether the proposed implementation of this factor is expected to be effective in tying the level of DSH reductions to the targeting of DSH payments to hospitals with high levels of uncompensated care. We believe that the proposed methodology, in using the mean uncompensated care cost level as the measure to identify hospitals with high levels of uncompensated care, captures the best balance in tying the level of DSH reductions to the targeting of DSH payments to such high level uncompensated care hospitals. Understanding potential data limitations and that the proposed methodology does not precisely distinguish how states direct DSH payments among hospitals that are identified as at or above the mean uncompensated care level, we are specifically soliciting comments on alternative methodologies regarding state targeting of DSH payments to hospitals with high levels of uncompensated care.

F. Factor 5—Section 1115 Budget Neutrality Factor (BNF)

The statute requires that we take into account the extent to which a state's

DSH allotment was included in the budget neutrality calculation for a coverage expansion that was approved under section 1115 demonstration authority as of July 31, 2009. These states possess full annual DSH allotments as calculated under section 1923(f) of the Act. Under an approved section 1115 demonstration, however, some states have limited authority to make DSH payments under section 1923 of the Act because all or a portion of their DSH allotment was included in the budget neutrality calculation for a coverage expansion under an approved section 1115 demonstration or to fund uncompensated care pools and/or safety net care pools. For applicable states, DSH payments under section 1923 of the Act are limited to the DSH allotment calculated under section 1923(f) of the Act less the allotment amount included in such a budget neutrality calculation. If a state's entire DSH allotment is included in such a budget neutrality calculation, it would have no available DSH funds with which to make DSH payments under section 1923 of the Act for the period of the demonstration.

Consistent with the statute, for states that include DSH allotment in budget neutrality calculations for coverage expansion under an approved section 1115 demonstration as of July 31, 2009, we propose to exclude from the DSH allotment reduction, for the HMF and the HUF factors, the amount of DSH allotment that each state currently continues to divert specifically for coverage expansion in the budget neutrality calculation. DSH allotment amounts included in budget neutrality calculations for non-coverage expansion purposes under approved demonstrations would still be subject to reduction. Uncompensated care pools and safety net care pools are considered non-coverage expansion purposes for the budget neutrality factor. For section 1115 demonstrations not approved as of

July 31, 2009, any DSH allotment amounts included in budget neutrality calculations, whether for coverage expansion or otherwise, under a later approval would also be subject to reduction.

We are proposing to determine for each reduction year if any portion of a state's DSH allotment qualifies for consideration under this factor. To qualify annually, CMS and the state would have to have included the state's DSH allotment in the budget neutrality calculation for a coverage expansion that was approved under section 1115 of the Act as of July 31, 2009, and the coverage expansion would have to still exist in the approved section 1115 demonstration at the time that reduction amounts are calculated for each FY. If a state had an amount for coverage expansion approved under a section 1115 of the Act as of July 31, 2009 but subsequently reduced this amount, the approved amount remaining under the section 1115 would not be subject to reduction.

The proposed DHRM would take into account the extent to which the DSH allotment for a state was included in the budget neutrality calculation for a demonstration approved under section 1115 of the Act as of July 31, 2009 by excluding from reduction under the HMF and HUF amounts diverted specifically for a coverage expansion and automatically assigning qualifying states an average reduction amount (that is, the average HUF and HMF of the state's respective state group) for any DSH allotment diverted for non-coverage expansion purposes and any amounts diverted for coverage expansion if the section 1115 demonstration was not approved as of July 31, 2009. DSH allotment reductions relating to two DHRM factors (the HUF and the HMF) are determined based on how states target DSH payments to certain hospitals. Since states that

diverted all or a portion of their DSH allotments would have limited or no relevant data for these two factors, we would be unable to evaluate how they spent the diverted portion of their DSH allotment for these targeting criteria. Accordingly, for diversion amounts subject to reduction, we are proposing to maintain the HUF and HMF formula for DSH payments for which qualifying states would have available data. Because we would not have DSH payment data for DSH allotment amounts diverted for non-coverage expansion (or for coverage expansions not approved as of July 31, 2009), we are proposing to assign average HUF and HMF reduction percentages for the portion of the DSH allotment that a state diverted for non-coverage expansion (or for coverage expansions not approved as of July 31, 2009) that it was consequently unable to use to target payments to disproportionate share hospitals. Instead of assigning the average percentage reduction to non-qualifying amounts, we considered using alternative percentages higher or lower than the average. However, these alternative percentages might provide an unintended benefit or penalty to these states for DSH diversions approved under section 1115 of the Act. We are seeking comment regarding the use of different percentages for the reductions to diversion amounts that do not qualify under the BNF and regarding alternative BNF methodologies that may provide preferable alternatives.

G. Illustration of DSH Health Reform Methodology (DHRM)

Table 1 and the values contained therein are provided only for purposes of illustrating the application of the DHRM and the associated DSH reduction factors described in this proposed rule to determine each state's DSH allotment reduction.

BILLING CODE 4120-01-P

TABLE 1: FY 2017 DSH HEALTH REFORM METHODOLOGY

*FOR ILLUSTRATION PURPOSES ONLY - FY 2017 DSH HEALTH REFORM METHODOLOGY							
	ILLUSTRATIVE DSH Reduction Factor Weighting Allocation						
	Total Reduction:	Uninsured Factor UPF	Hi Volume Factor HMF	High Level Factor HUF	TOTAL		
		50.00%	25.00%	25.00%	100.00%		
	Total Reg. DSH Reduction:	\$987,536,279	\$493,768,140	\$493,768,140	\$1,975,072,559		
LOW DSH Adj. Factor	Total Low DSH Reduction:	\$12,463,721	\$6,231,860	\$6,231,860	\$24,927,441		
27.83%	TOTAL:	\$1,000,000,000	\$500,000,000	\$500,000,000	\$2,000,000,000		
A	B	C	D	E	F	G	H
STATE	Unreduced FY 2017 DSH Allotment (Estimate)	Reduction Based on UPF Uninsured Factor	Reduction Based on HMF High Volume Factor	Reduction Based On HUF High Level Factor	Total Reduction C + D + E	Reduction Amount As Percentage of Unreduced DSH Allotment F/B	FY 2017 Reduced Allotment B - F
Alabama	\$337,648,430	\$24,336,783	\$22,311,475	\$12,205,968	\$58,854,226	17.43%	\$278,794,204
Arizona	\$111,176,922	\$7,137,605	\$3,547,314	\$540,535	\$11,225,454	10.10%	\$99,951,468
California	\$1,203,730,377	\$84,684,522	\$27,524,140	\$41,213,794	\$153,422,456	12.75%	\$1,050,307,921
Colorado	\$101,569,041	\$8,631,358	\$7,177,442	\$2,752,327	\$18,561,127	18.27%	\$83,007,914
Connecticut	\$219,608,734	\$27,749,875	\$8,953,379	\$12,499,484	\$49,202,738	22.40%	\$170,405,996
District of Columbia	\$67,255,174	\$11,161,638	\$948,482	\$4,788,317	\$16,898,437	25.13%	\$50,356,737
Florida	\$219,608,734	\$11,604,440	\$7,724,576	\$14,761,318	\$34,090,334	15.52%	\$185,518,400
Georgia	\$295,099,237	\$16,322,138	\$9,642,846	\$10,330,646	\$36,295,629	12.30%	\$258,803,608

*FOR ILLUSTRATION PURPOSES ONLY - FY 2017 DSH HEALTH REFORM METHODOLOGY							
	ILLUSTRATIVE DSH Reduction Factor Weighting Allocation						
	Total Reduction:	Uninsured Factor UPF	Hi Volume Factor HMF	High Level Factor HUF	TOTAL		
		50.00%	25.00%	25.00%	100.00%		
	Total Reg. DSH Reduction:	\$987,536,279	\$493,768,140	\$493,768,140	\$1,975,072,559		
LOW DSH Adj. Factor	Total Low DSH Reduction:	\$12,463,721	\$6,231,860	\$6,231,860	\$24,927,441		
27.83%	TOTAL:	\$1,000,000,000	\$500,000,000	\$500,000,000	\$2,000,000,000		
A	B	C	D	E	F	G	H
Illinois	\$236,079,390	\$21,211,561	\$21,228,808	\$2,226,180	\$44,666,550	18.92%	\$191,412,840
Indiana	\$234,706,837	\$17,212,117	\$7,854,285	\$2,660,409	\$27,726,811	11.81%	\$206,980,026
Kansas	\$45,294,302	\$3,871,800	\$3,187,693	\$1,866,967	\$8,926,460	19.71%	\$36,367,842
Kentucky	\$159,216,333	\$16,485,287	\$7,021,414	\$6,556,338	\$30,063,039	18.88%	\$129,153,294
Louisiana	\$752,888,159	\$44,629,718	\$8,761,366	\$28,576,335	\$81,967,418	10.89%	\$670,920,741
Maine	\$115,294,586	\$9,949,588	\$1,191,719	\$1,053,779	\$12,195,085	10.58%	\$103,099,501
Maryland	\$83,725,829	\$9,314,506	\$3,064,435	\$2,498,384	\$14,877,325	17.77%	\$68,848,504
Massachusetts	\$334,903,321	\$89,406,469	\$8,587,673	\$7,322,652	\$105,316,795	31.45%	\$229,586,526
Michigan	\$290,981,574	\$29,838,010	\$17,552,322	\$19,346,010	\$66,736,341	22.93%	\$224,245,233
Mississippi	\$167,451,660	\$10,119,288	\$4,755,050	\$2,557,905	\$17,432,243	10.41%	\$150,019,417
Missouri	\$520,198,191	\$39,063,452	\$29,634,901	\$23,891,614	\$92,589,967	17.80%	\$427,608,224
Nevada	\$50,784,519	\$2,924,122	\$436,562	\$544,246	\$3,904,930	7.69%	\$46,879,589
New Hampshire	\$175,795,169	\$16,765,244	\$2,912,141	\$2,025,265	\$21,702,651	12.35%	\$154,092,518
New Jersey	\$706,865,615	\$56,618,281	\$44,292,058	\$52,834,997	\$153,745,336	21.75%	\$553,120,279
New York	\$1,763,732,651	\$177,505,591	\$78,224,710	\$73,714,317	\$329,444,617	18.68%	\$1,434,288,034
North Carolina	\$323,922,884	\$21,676,870	\$14,090,407	\$20,538,422	\$56,305,699	17.38%	\$267,617,185

*FOR ILLUSTRATION PURPOSES ONLY - FY 2017 DSH HEALTH REFORM METHODOLOGY							
	ILLUSTRATIVE DSH Reduction Factor Weighting Allocation						
	Total Reduction:	Uninsured Factor UPF	Hi Volume Factor HMF	High Level Factor HUF	TOTAL		
		50.00%	25.00%	25.00%	100.00%		
	Total Reg. DSH Reduction:	\$987,536,279	\$493,768,140	\$493,768,140	\$1,975,072,559		
LOW DSH Adj. Factor	Total Low DSH Reduction:	\$12,463,721	\$6,231,860	\$6,231,860	\$24,927,441		
27.83%	TOTAL:	\$1,000,000,000	\$500,000,000	\$500,000,000	\$2,000,000,000		
A	B	C	D	E	F	G	H
Ohio	\$446,080,243	\$46,702,161	\$25,434,391	\$29,795,707	\$101,932,258	22.85%	\$344,147,985
Pennsylvania	\$616,277,012	\$63,782,334	\$32,922,465	\$24,331,996	\$121,036,794	19.64%	\$495,240,218
Rhode Island	\$71,372,839	\$8,426,370	\$6,425,719	\$1,860,620	\$16,712,709	23.42%	\$54,660,130
South Carolina	\$359,609,303	\$23,233,999	\$22,965,009	\$23,842,222	\$70,041,229	19.48%	\$289,568,074
Tennessee*	\$0	\$0	\$0	\$0	\$0	0.00%	\$0
Texas	\$1,050,004,264	\$48,245,203	\$50,044,327	\$49,773,279	\$148,062,808	14.10%	\$901,941,456
Vermont	\$24,705,984	\$4,369,886	\$1,875,609	\$775,093	\$7,020,587	28.42%	\$17,685,397
Virginia	\$96,196,942	\$7,735,598	\$122,311	\$3,188,924	\$11,046,833	11.48%	\$85,150,109
Washington	\$203,138,079	\$19,249,651	\$12,038,303	\$10,449,879	\$41,737,833	20.55%	\$161,400,246
West Virginia	\$74,117,949	\$7,570,819	\$1,314,810	\$2,444,211	\$11,329,840	15.29%	\$62,788,109
Total Regular DSH States	\$11,459,040,284	\$987,536,279	\$493,768,140	\$493,768,140	\$1,975,072,559	17.24%	\$9,483,967,725
LOW DSH STATES							
Alaska	\$22,366,812	\$258,424	\$851,319	\$136,279	\$1,246,022	5.57%	\$21,120,790
Arkansas	\$47,367,170	\$799,743	\$33,070	\$1,146,287	\$1,979,100	4.18%	\$45,388,070
Delaware	\$9,940,805	\$254,209	\$205,569	\$94,226	\$554,005	5.57%	\$9,386,800

*FOR ILLUSTRATION PURPOSES ONLY - FY 2017 DSH HEALTH REFORM METHODOLOGY							
	ILLUSTRATIVE DSH Reduction Factor Weighting Allocation						
	Total Reduction:	Uninsured Factor UPF	Hi Volume Factor HMF	High Level Factor HUF	TOTAL		
		50.00%	25.00%	25.00%	100.00%		
	Total Reg. DSH Reduction:	\$987,536,279	\$493,768,140	\$493,768,140	\$1,975,072,559		
LOW DSH Adj. Factor	Total Low DSH Reduction:	\$12,463,721	\$6,231,860	\$6,231,860	\$24,927,441		
27.83%	TOTAL:	\$1,000,000,000	\$500,000,000	\$500,000,000	\$2,000,000,000		
A	B	C	D	E	F	G	H
Hawaii	\$10,701,306	\$403,540	\$326,243	\$78,866	\$808,649	7.56%	\$9,892,657
Idaho	\$18,049,095	\$264,628	\$49,829	\$87,268	\$401,724	2.23%	\$17,647,371
Iowa	\$43,242,210	\$1,394,059	\$115,140	\$1,361,179	\$2,870,379	6.64%	\$40,371,831
Minnesota	\$82,011,647	\$2,774,292	\$218,017	\$565,875	\$3,558,184	4.34%	\$78,453,463
Montana	\$12,463,647	\$174,295	\$522,983	\$208,536	\$905,813	7.27%	\$11,557,834
Nebraska	\$31,072,684	\$638,999	\$157,417	\$641,315	\$1,437,730	4.63%	\$29,634,954
New Mexico	\$22,366,812	\$306,213	\$136,653	\$45,268	\$488,134	2.18%	\$21,878,678
North Dakota	\$10,488,492	\$265,499	\$54,018	\$11,994	\$331,511	3.16%	\$10,156,981
Oklahoma	\$39,763,220	\$514,542	\$1,587,344	\$446,030	\$2,547,915	6.41%	\$37,215,305
Oregon	\$49,704,028	\$1,015,201	\$788,620	\$931,845	\$2,735,666	5.50%	\$46,968,362
South Dakota	\$12,127,506	\$245,843	\$18,050	\$24,036	\$287,929	2.37%	\$11,839,577
Utah	\$21,541,402	\$341,688	\$1,159,479	\$446,117	\$1,947,284	9.04%	\$19,594,118
Wisconsin	\$103,801,167	\$2,808,415	\$436	\$1,298	\$2,810,149	2.71%	\$100,991,018
Wyoming	\$248,521	\$4,131	\$7,674	\$5,441	\$17,245	6.94%	\$231,276
Total Low DSH States	\$537,256,524	\$12,463,721	\$6,231,860	\$6,231,860	\$24,927,441	4.64%	\$512,329,083

*FOR ILLUSTRATION PURPOSES ONLY - FY 2017 DSH HEALTH REFORM METHODOLOGY							
		ILLUSTRATIVE DSH Reduction Factor Weighting Allocation					
	Total Reduction:	Uninsured Factor UPF	Hi Volume Factor HMF	High Level Factor HUF	TOTAL		
		50.00%	25.00%	25.00%	100.00%		
	Total Reg. DSH Reduction:	\$987,536,279	\$493,768,140	\$493,768,140	\$1,975,072,559		
LOW DSH Adj. Factor	Total Low DSH Reduction:	\$12,463,721	\$6,231,860	\$6,231,860	\$24,927,441		
27.83%	TOTAL:	\$1,000,000,000	\$500,000,000	\$500,000,000	\$2,000,000,000		
A	B	C	D	E	F	G	H
National Total	\$11,996,296,808	\$1,000,000,000	\$500,000,000	\$500,000,000	\$2,000,000,000	16.67%	\$9,996,296,808

*Under section 1923(f)(6)(A)(vi) of the Act the DSH allotment for Tennessee is established at \$53.1 million per year for FY 2015 through FY 2025. Therefore, Tennessee is not subject to reductions under section 1923(f)(7) of the Act.

BILLING CODE 4120-01-C

IV. Collection of Information Requirements

Beginning with each state's Medicaid state plan for rate year 2005, each state must submit to CMS (at the same time as it submits the completed DSH audit as required under § 455.304) the data specified under § 447.299 for each DSH hospital to which the state made a DSH payment. While the reported information will allow CMS to verify the appropriateness of such payments, the reporting requirements and burden are currently approved by OMB under control number 0938-0746 (CMS-R-266). Importantly, this rule does not propose any new/revised information collection requirements or burden pertaining to § 447.299.

Although mentioned earlier in this preamble, this rule does not propose any new/revised SPA or auditing requirements or burden nor any new/revised information collection requirements or burden associated with CMS-64 (control number 0938-1265) or CMS-2552 (control number 0938-0050).

Since this rule does not propose any new or revised information collection requirements or burden, it need not be reviewed by OMB under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Analysis

A. Statement of Need

The Affordable Care Act amended the Act by requiring aggregate reductions to state Medicaid DSH allotments annually from FY 2014 through FY 2020. Subsequent legislation extended the reductions, modified the amount of the reductions, and delayed the start of the reductions until FY 2018. The most recent related amendments to the statute were through the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10, enacted April 16, 2015). This proposed rule delineates the DHRM to implement the annual reductions for FY 2018 through FY 2025.

B. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). This rule has been designated an "economically significant" rule measured by the \$100 million threshold, under section 3(f)(1) of Executive Order 12866. Accordingly, we have prepared a Regulatory Impact Analysis (RIA) that, to the best of our ability, presents the costs and benefits of the rulemaking.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2017, that threshold is approximately \$148 million. This final rule would not mandate any requirements for state, local, or tribal governments, nor would it affect private sector costs.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this rule does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

The RFA requires agencies to analyze options for regulatory relief of small entities, and to prepare an Initial Regulatory Flexibility Analysis (IRFA), for proposed rules that would have a "significant economic impact on a substantial number of small entities." For purposes of the RFA, small entities

include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than \$7.5 million to \$38.5 million in any 1 year. Individuals and states are not included in the definition of a small entity.

We are not preparing an IRFA because we have determined, and the Secretary certifies, that this proposed rule would not have a significant economic impact on a substantial number of small entities (including hospitals and providers) because states still have considerable flexibility to determine DSH state plan payment methodologies.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

Executive Order 13175 directs agencies to consult with Tribal officials prior to the formal promulgation of regulations having tribal implications. This proposed rule has tribal implications, and in accordance with E.O. 13175 and the CMS Tribal Consultation Policy (December, 2015), CMS will consult with Tribal officials prior to the formal promulgation of this regulation.

C. Anticipated Effects

1. Effects on State Medicaid Programs

We anticipate, effective for FY 2018, that the proposed DSH allotment reductions would have a direct effect on the ability for some or all states to

maintain state-wide Medicaid DSH payments at FY 2017 levels. Federal share DSH allotments, which are published by CMS in an annual **Federal Register** notice, limit the amount of federal financial participation (FFP) in the aggregate that states can pay annually in DSH payments to hospitals. This proposed rule would reduce state DSH allotment amounts, and therefore, would limit the states' ability to make DSH payments and claim FFP for DSH payments at FY 2017 levels. By statute, the rule would reduce state DSH allotments by \$43,000,000,000 for FY 2018 through FY 2025. We anticipate that the rule would reduce total federal financial participation claimed by states by similar amounts, although it may not equal the exact amount of the allotment reductions. Due to the complexity of the interaction among the proposed DHRM methodology, state DSH allotments, DHRM data, future state DSH payment levels and methodologies for these years, we cannot provide a specific estimate of the total federal financial impact for each year.

The proposed rule utilizes a DHRM that would mitigate the negative impact on states that continue to have high percentages of uninsured and are targeting DSH payments to hospitals that have a high volume of Medicaid patients and to hospitals with high levels of uncompensated care.

2. Effects on Providers

We anticipate that the final rule would affect certain providers through the reduction of state DSH payments. We cannot, however, estimate the impact on individual providers or groups of providers. This proposed rule

would not affect the considerable flexibility afforded states in setting DSH state plan payment methodologies to the extent that these methodologies are consistent with section 1923(c) of the Act and all other applicable statutes and regulations. States would retain the ability to preserve existing DSH payment methodologies or to propose modified methodologies by submitting state plan amendments to us. Some states may determine that implementing a proportional reduction in DSH payments for all qualifying hospitals is the preferred method to account for the reduced allotment. Alternatively, states could determine that the best action is to propose a methodology that would direct DSH payments reductions to hospitals that do not have high Medicaid volume and do not have high levels of uncompensated care. Regardless, the rule would incentivize states to target DSH payments to hospitals that are most in need of Medicaid DSH funding based on their serving a high volume of Medicaid inpatients and having a high level of uncompensated care.

This proposed rule also does not affect the calculation of the hospital-specific DSH limit established at section 1923(g) of the Act. This hospital-specific limit requires that Medicaid DSH payments to a qualifying hospital not exceed the costs incurred by that hospital for providing inpatient and outpatient hospital services furnished during the year to Medicaid patients and individuals who have no health insurance or other source of third party coverage for the services provided during the year, less applicable revenues for those services.

Although this rule would reduce state DSH allotments, the management of the reduced allotments still largely remains with the states. Given that states would retain the same flexibility to design DSH payment methodologies under the state plan and that individual hospital-specific DSH payment limits would not be affected, we cannot predict whether and how states would exercise their flexibility in setting DSH payments to account for their reduced DSH allotment and how this would affect individual providers or specific groups of providers.

D. Alternatives Considered

The statute specifies the annual DSH allotment reduction amounts. Therefore, we were unable to consider alternative reduction amounts. However, we did consider various methodological alternatives to the DHRM throughout each individual section in detail. These proposed alternatives relate to various weight assignments to reduction factors identified in the statute, utilizing various alternative data sources for uncompensated cost and uninsured data, and proposing a reduction cap methodology in order to limit the reduction amount to be applied to each state's total unreduced DSH allotment.

E. Accounting Statement and Table

As required by OMB Circular A-4 (available at www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf), we have prepared an accounting statement table showing the classification of the impacts associated with implementation of this proposed rule.

TABLE 2—ACCOUNTING STATEMENT

Category	Estimates	Units		
		Year dollar	Discount rate %	Period covered
Transfers				
Annualized Reductions in Disproportionate Share Hospital Allotment (in millions)	– 5,049.1 – 5,232.5	2017 2017	7 3	2018–2025 2018–2025
From Whom to Whom	Federal Government to the States due to assumed reduced number of uninsured and uncompensated care.			

F. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. Section 2(a) of Executive Order 13771 requires an agency, unless prohibited by law, to identify at least

two existing regulations to be repealed when the agency publicly proposes for notice and comment, or otherwise promulgates, a new regulation. In furtherance of this requirement, section 2(c) of Executive Order 13771 requires that the new incremental costs associated with new regulations shall, to

the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations. OMB's implementation guidance, issued on April 5, 2017, explains that "Federal spending regulatory actions that cause only income transfers between taxpayers and

program beneficiaries (for example, regulations associated with . . . Medicare spending) are considered ‘transfer rules’ and are not covered by E.O. 13771 However . . . such regulatory actions may impose requirements apart from transfers. . . . In those cases, the actions would need to be offset to the extent they impose more than de minimis costs. Examples of ancillary requirements that may require offsets include new reporting or recordkeeping requirements.” It has been determined that this proposed rule is a transfer rule that does not impose more than de minimis costs as described previously and thus is not a regulatory action for the purposes of E.O. 13771.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 447—PAYMENTS FOR SERVICES

■ 1. The authority citation for part 447 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

- 2. Section 447.294 is amended by—
- a. Revising the section heading;
- b. Revising paragraph (a);
- c. Amending paragraph (b) by adding the definition of “Total hospital cost”; and
- d. Revising paragraphs (d), (e) introductory text, (e)(3)(i) and (5)(i) through (iii), and (f).

The revisions and addition reads as follows:

§ 447.294 Medicaid disproportionate share hospital (DSH) allotment reductions.

(a) *Basis and purpose.* This section sets forth the DSH health reform methodology (DHRM) for calculating State-specific annual DSH allotment reductions as required under section 1923(f) of the Act.

(b) *Total hospital cost* means the total annual costs incurred by a hospital for furnishing inpatient and outpatient hospital services.

(d) *State data submission requirements.* States are required to submit the mean MIUR, determined in accordance with section 1923(b)(1)(A) of the Act, for all hospitals receiving Medicaid payments in the State and the value of one standard deviation above such mean. The State must provide this data to CMS by June 30 of each year. To determine which state plan rate year’s data the state must submit, subtract 3 years from the calendar year in which the data is due.

(e) *DHRM methodology.* Section 1923(f)(7) of the Act requires aggregate

annual reduction amounts as specified in paragraph (f) of this section to be reduced through the DHRM. The DHRM is calculated on an annual basis based on the most recent data available to CMS at the time of the calculation. The DHRM is determined as follows:

* * * * *

(3) * * *

(i) Dividing each State’s preliminary unreduced DSH allotment by their respective total estimated Medicaid service expenditures for the applicable fiscal year.

* * * * *

(5) * * *

(i) UPF—50 percent.

(ii) HMF—25 percent.

(iii) HUF—25 percent.

* * * * *

(f) *Annual DSH allotment reduction application.* For each fiscal year identified in section 1923(f)(7)(A)(ii) of the Act, CMS will subtract the State-specific DSH allotment amount determined in paragraph (e)(14) of this section from that State’s final unreduced DSH allotment. This amount is the State’s final DSH allotment for the fiscal year.

May 26, 2017.

Seema Verma,
Administrator, Centers for Medicare & Medicaid Services.

Dated: July 24, 2017.

Thomas Price,
Secretary, Department of Health and Human Services.

[FR Doc. 2017–15962 Filed 7–27–17; 8:45 am]

BILLING CODE 4120–01–P

Notices

Federal Register

Vol. 82, No. 144

Friday, July 28, 2017

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

Animal and Plant Health Inspection Service

[Docket No. APHIS–2017–0015]

Bayer CropScience LP: Determination of Nonregulated Status of Canola Genetically Engineered for Male Sterility and Glufosinate-Ammonium Resistance

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination to extend the nonregulated status of InVigor® MS8 canola (hereinafter MS8 canola) to Bayer CropSciences LP's (Bayer) canola event MS11 which has been genetically engineered for male sterility and resistance to the herbicide glufosinate-ammonium using the same mechanism of action as Bayer's MS8 canola. Our determination is based on our evaluation of data submitted by Bayer in its petition for a determination of nonregulated status, our analysis of publically available scientific data, and comments received from the public on the petition for nonregulated status and its associated environmental assessment and plant pest risk similarity assessment. This notice also announces the availability of our written determination and finding of no significant impact.

DATES: Effective July 28, 2017.

FOR FURTHER INFORMATION CONTACT: Ms. Cindy Eck, Document Control Officer/ Team Leader, Policy Coordination Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road, Unit 147, Riverdale, MD 20737–1236; (301) 851–3954, email: cynthia.a.eck@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 7 CFR part 340, “Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests,” regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered (GE) organisms and products are considered “regulated articles.”

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. Paragraphs (b) and (c) of § 340.6 describe the form that a petition for a determination of nonregulated status must take and the information that must be included in the petition.

APHIS received a request for an extension of the determination of nonregulated status of MS8 canola to canola designated as canola event MS11 (APHIS Petition Number 16–235–01p) from Bayer CropScience LP (Bayer) of Research Triangle Park, NC. MS11 canola expresses male sterility and resistance to the herbicide glufosinate-ammonium. In its request, Bayer stated that this canola is similar to the antecedent organism MS8 canola and, based on the similarity to the antecedent organism, is unlikely to pose a plant pest risk and, therefore, should not be a regulated article under APHIS' regulations in 7 CFR part 340.

In a notice¹ published in the **Federal Register** on April 12, 2017 (82 FR 17625–17626, Docket No. APHIS–2017–0015), APHIS announced the availability of the Bayer's petition, draft environmental assessment, preliminary finding of no significant impact, draft plant pest risk similarity assessment, and preliminary determination for nonregulated status for public comment. We solicited comments on the notice for 30 days ending May 12, 2017. We extended the deadline for comments

until May 30, 2017, in a document published in the **Federal Register** on May 10, 2017 (82 FR 21790–21791, Docket No. APHIS–2017–0015). We received 5 comments by that date. The comments are discussed in the finding of no significant impact (FONSI) that accompanies this notice.

Determination of Nonregulated Status

Based on APHIS' analysis of field and laboratory data submitted by Bayer, references provided in the petitions, peer-reviewed publications, information analyzed in the environmental assessment, the plant pest risk similarity assessment (PPRSA), comments provided by the public, and APHIS' evaluation of and response to those comments, APHIS has determined that MS11 canola is unlikely to pose a plant pest risk. Accordingly, the petition requesting a determination of nonregulated status is approved and MS11 canola is no longer subject to our regulations governing the introduction of certain genetically engineered organisms and to the plant pest provisions of the Plant Protection Act.

Copies of the signed determination document and the signed record of decision, as well as copies of the final environmental assessment, FONSI, and the PPRSA are available as indicated in the **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT** sections of this notice.

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 25th day of July 2017.

Christine Zakarka,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2017–15949 Filed 7–27–17; 8:45 am]

BILLING CODE 3410–34–P

¹To view the notice, the petition, the comments we received, and other supporting documents, go to <http://www.regulations.gov/> #!docketDetail;D=APHIS-2017-0015.

DEPARTMENT OF AGRICULTURE**Food and Nutrition Service****Child and Adult Care Food Program: National Average Payment Rates, Day Care Home Food Service Payment Rates, and Administrative Reimbursement Rates for Sponsoring Organizations of Day Care Homes for the Period July 1, 2017 Through June 30, 2018**

AGENCY: Food and Nutrition Service, USDA.

ACTION: Notice.

SUMMARY: This notice announces the annual adjustments to the national average payment rates for meals and snacks served in child care centers, outside-school-hours care centers, at-risk afterschool care centers, and adult day care centers; the food service payment rates for meals and snacks served in day care homes; and the administrative reimbursement rates for sponsoring organizations of day care homes, to reflect changes in the Consumer Price Index. Further adjustments are made to these rates to reflect the higher costs of providing meals in the States of Alaska and Hawaii. The adjustments contained in this notice are made on an annual basis each July, as required by the laws and regulations governing the Child and Adult Care Food Program.

DATES: These rates are effective from July 1, 2017 through June 30, 2018.

FOR FURTHER INFORMATION CONTACT: Jessica Saracino, Branch Chief, Program Monitoring and Operational Support Division, Child Nutrition Programs, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Room 640, Alexandria, Virginia 22302-1594.

SUPPLEMENTARY INFORMATION:**Definitions**

The terms used in this notice have the meanings ascribed to them in the Child and Adult Care Food Program regulations, 7 CFR part 226.

Background

Pursuant to sections 4, 11, and 17 of the Richard B. Russell National School Lunch Act (42 U.S.C. 1753, 1759a and 1766), section 4 of the Child Nutrition Act of 1966 (42 U.S.C. 1773) and 7 CFR 226.4, 226.12 and 226.13 of the Program regulations, notice is hereby given of the new payment rates for institutions participating in the Child and Adult Care Food Program (CACFP). These rates are in effect during the period July 1, 2017 through June 30, 2018.

As provided for under the law, all rates in the CACFP must be revised annually, on July 1, to reflect changes in the Consumer Price Index (CPI), published by the Bureau of Labor Statistics of the United States Department of Labor, for the most recent 12-month period. In accordance with this mandate, the United States Department of Agriculture (USDA) last published the adjusted national average payment rates for centers, the food service payment rates for day care homes, and the administrative reimbursement rates for sponsoring organizations of day care homes, for the period from July 1, 2016 through June 30, 2017, on August 5, 2016, in the **Federal Register** at 81 FR 51840.

Adjusted Payments

The following national average payment factors and food service payment rates for meals and snacks are in effect from July 1, 2017 through June 30, 2018. All amounts are expressed in dollars or fractions thereof. Due to a higher cost of living, the reimbursements for Alaska and Hawaii are higher than those for all other States. The District of Columbia, Virgin Islands, Puerto Rico, and Guam use the figures specified for the contiguous States. These rates do not include the value of USDA Foods or cash-in-lieu of USDA Foods which institutions receive as additional assistance for each lunch or supper served to participants under the Program. A notice announcing the value of USDA Foods and cash-in-lieu of USDA Foods is published separately in the **Federal Register**.

National Average Payment Rates for Centers

Payments for breakfasts served are: *Contiguous States*—paid rate—30 cents (1 cent increase from 2016–2017 annual level), reduced price rate—145 cents (4 cents increase); *Alaska*—paid rate—45 cents (1 cent increase), reduced price rate—249 cents (6 cents increase), free rate—279 cents (6 cents increase); *Hawaii*—paid rate—34 cents (1 cent increase), reduced price rate—173 cents (4 cents increase), free rate—203 cents (4 cents increase).

Payments for lunch or supper served are: *Contiguous States*—paid rate—31 cents (1 cent increase from 2016–2017 annual level), reduced price rate—283 cents (7 cents increase), free rate—323 cents (7 cents increase); *Alaska*—paid rate—50 cents (1 cent increase), reduced price rate—484 cents (12 cents increase), free rate—524 cents (12 cents increase); *Hawaii*—paid rate—36 cents (1 cent increase), reduced price rate—

338 cents (9 cents increase), free rate—378 cents (9 cents increase).

Payments for snack served are: *Contiguous States*—paid rate—8 cents (1 cent increase from 2016–2017 annual level), reduced price rate—44 cents (1 cent increase), free rate—88 cents (2 cents increase); *Alaska*—paid rate—13 cents (1 cent increase), reduced price rate—72 cents (2 cents increase), free rate—144 cents (4 cents increase); *Hawaii*—paid rate—9 cents (no change), reduced price rate—52 cents (2 cents increase), free rate—104 cents (3 cents increase).

Food Service Payment Rates for Day Care Homes

Payments for breakfast served are: *Contiguous States*—tier I—131 cents (no change from 2016–2017 annual level) and tier II—48 cents (no change); *Alaska*—tier I—209 cents (no change) and tier II—74 cents (no change); *Hawaii*—tier I—152 cents (1 cent decrease) and tier II—55 cents (no change).

Payments for lunch and supper served are: *Contiguous States*—tier I—246 cents (no change from 2016–2017 annual level) and tier II—148 cents (1 cent decrease); *Alaska*—tier I—399 cents (no change) and tier II—240 cents (1 cent decrease); *Hawaii*—tier I—288 cents (no change) and tier II—174 cents (no change).

Payments for snack served are: *Contiguous States*—tier I—73 cents (no change from 2016–2017 annual level) and tier II—20 cents (no change); *Alaska*—tier I—119 cents (no change) and tier II—32 cents (1 cent decrease); *Hawaii*—tier I—85 cents (1 cent decrease) and tier II—23 cents (no change).

Administrative Reimbursement Rates for Sponsoring Organizations of Day Care Homes

Monthly administrative payments to sponsors for each sponsored day care home are: *Contiguous States*—initial 50 homes—114 dollars (2 dollar increase from 2016–2017 annual level), next 150 homes—87 dollars (1 dollar increase), next 800 homes—68 dollars (1 dollar increase), each additional home—60 dollars (1 dollar increase); *Alaska*—initial 50 homes—185 dollars (3 dollar increase), next 150 homes—141 dollars (2 dollar increase), next 800 homes—110 dollars (2 dollar increase), each additional home—97 dollars (2 dollar increase); *Hawaii*—initial 50 homes—134 dollars (3 dollar increase), next 150 homes—102 dollars (2 dollar increase), next 800 homes—80 dollars (2 dollar increase), each additional home—70 dollars (1 dollar increase).

Payment Chart

The following chart illustrates the national average payment factors and

food service payment rates for meals and snacks in effect from July 1, 2017 through June 30, 2018.

CHILD AND ADULT CARE FOOD PROGRAM (CACFP)							
Per Meal Rates in Whole or Fractions of U.S. Dollars							
Effective from July 1, 2017- June 30, 2018							
CENTERS		BREAKFAST		LUNCH AND SUPPER ¹		SUPPLEMENT	
CONTIGUOUS STATES	PAID	0.30		0.31		0.08	
	REDUCED PRICE	1.45		2.83		0.44	
	FREE	1.75		3.23		0.88	
ALASKA	PAID	0.45		0.50		0.13	
	REDUCED PRICE	2.49		4.84		0.72	
	FREE	2.79		5.24		1.44	
HAWAII	PAID	0.34		0.36		0.09	
	REDUCED PRICE	1.73		3.38		0.52	
	FREE	2.03		3.78		1.04	
DAY CARE HOMES		BREAKFAST		LUNCH AND SUPPER		SUPPLEMENT	
		TIER I	TIER II	TIER I	TIER II	TIER I	TIER II
CONTIGUOUS STATES		1.31	0.48	2.46	1.48	0.73	0.20
ALASKA		2.09	0.74	3.99	2.40	1.19	0.32
HAWAII		1.52	0.55	2.88	1.74	0.85	0.23
ADMINISTRATIVE REIMBURSEMENT RATES FOR SPONSORING ORGANIZATIONS OF DAY CARE HOMES				Initial 50	Next 150	Next 800	Each Additional
Per Home/Per Month Rates in U.S. Dollars							
CONTIGUOUS STATES				114	87	68	60
ALASKA				185	141	110	97
HAWAII				134	102	80	70

¹These rates do not include the value of USDA Foods or cash-in-lieu of USDA Foods which institutions receive as additional assistance for each CACFP lunch or supper served to participants. A notice announcing the value of USDA Foods and cash-in-lieu of USDA Foods is published separately in the *Federal Register*.

The changes in the national average payment rates for centers reflect a 2.31 percent increase during the 12-month period from May 2016 to May 2017 (from 262.074 in May 2016, as previously published in the **Federal Register**, to 268.128 in May 2017) in the food away from home series of the CPI for All Urban Consumers.

The changes in the food service payment rates for day care homes reflect a 0.16 percent decrease during the 12-month period from May 2016 to May 2017 (from 239.354 in May 2016, as previously published in the **Federal**

Register, to 238.964 in May 2017) in the food at home series of the CPI for All Urban Consumers.

The changes in the administrative reimbursement rates for sponsoring organizations of day care homes reflect a 1.87 percent increase during the 12-month period, May 2016 to May 2017 (from 240.236 in May 2016, as previously published in the **Federal Register**, to 240.733 in May 2017) in the series for all items of the CPI for All Urban Consumers.

The total amount of payments available to each State agency for

distribution to institutions participating in CACFP is based on the rates contained in this notice.

This action is not a rule as defined by the Regulatory Flexibility Act (5 U.S.C. 601–612) and thus is exempt from the provisions of that Act. This notice has been determined to be exempt under Executive Order 12866.

CACFP is listed in the Catalog of Federal Domestic Assistance under No. 10.558 and is subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials.

This notice has been determined to be not significant and was not reviewed by the Office of Management and Budget (OMB) in conformance with Executive Order 12866.

This notice imposes no new reporting or recordkeeping provisions that are subject to OMB review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3518).

Authority: Sections 4(b)(2), 11a, 17(c) and 17(f)(3)(B) of the Richard B. Russell National School Lunch Act (42 U.S.C. 1753(b)(2), 1759a, 1766(f)(3)(B)) and section 4(b)(1)(B) of the Child Nutrition Act of 1966 (42 U.S.C. 1773(b)(1)(B)).

Dated: July 13, 2017.

Jessica Shahin,

Acting Administrator, Food and Nutrition Service.

[FR Doc. 2017–15950 Filed 7–27–17; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

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

AGENCY: Food and Nutrition Service, USDA

ACTION: Notice.

SUMMARY: This Notice announces the annual adjustments to the “national average payments,” the amount of money the Federal Government provides States for lunches, afterschool snacks, and breakfasts served to children participating in the National School Lunch and School Breakfast Programs; to the “maximum reimbursement rates,” the maximum per lunch rate from Federal funds that a State can provide a school food authority for lunches served to children participating in the National School Lunch Program; and to the rate of reimbursement for a half-pint of milk served to non-needy children in a school or institution that participates in the Special Milk Program for Children. The payments and rates are prescribed on an annual basis each July. The annual payments and rates adjustments for the National School Lunch and School Breakfast Programs reflect changes in the Food Away From Home series of the Consumer Price Index for All Urban Consumers. The annual rate adjustment for the Special Milk Program reflects changes in the Producer Price Index for Fluid Milk Products.

DATES: These rates are effective from July 1, 2017 through June 30, 2018.

FOR FURTHER INFORMATION CONTACT:

Jessica Saracino, Branch Chief, Program Monitoring and Operational Support Division, Child Nutrition Programs, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Room 640, Alexandria, VA 22302–1594.

SUPPLEMENTARY INFORMATION:

Background

*Special Milk Program for Children—*Pursuant to section 3 of the Child Nutrition Act of 1966, as amended (42 U.S.C. 1772), the Department announces the rate of reimbursement for a half-pint of milk served to non-needy children in a school or institution that participates in the Special Milk Program for Children. This rate is adjusted annually to reflect changes in the Producer Price Index for Fluid Milk Products, published by the Bureau of Labor Statistics of the Department of Labor.

For the period July 1, 2017 through June 30, 2018, the rate of reimbursement for a half-pint of milk served to a non-needy child in a school or institution that participates in the Special Milk Program is 20.75 cents. This reflects an increase of 1 cent from the School Year (SY) 2016–17 level, based on the 4.21 percent increase in the Producer Price Index for Fluid Milk Products from May 2016 to May 2017 (from a level of 216.1 in May 2016, as previously published in the **Federal Register** to 225.2 in May 2017).

As a reminder, schools or institutions with pricing programs that elect to serve milk free to eligible children continue to receive the average cost of a half-pint of milk (the total cost of all milk purchased during the claim period divided by the total number of purchased half-pints) for each half-pint served to an eligible child.

*National School Lunch and School Breakfast Programs—*Pursuant to sections 11 and 17A of the Richard B. Russell National School Lunch Act, (42 U.S.C. 1759a and 1766a), and section 4 of the Child Nutrition Act of 1966 (42 U.S.C. 1773), the Department annually announces the adjustments to the National Average Payment Factors and to the maximum Federal reimbursement rates for lunches and afterschool snacks served to children participating in the National School Lunch Program and breakfasts served to children participating in the School Breakfast Program. Adjustments are prescribed each July 1, based on changes in the Food Away From Home series of the Consumer Price Index for All Urban Consumers, published by the Bureau of Labor Statistics of the Department of Labor. The changes in the national

average payment rates for schools and residential child care institutions for the period July 1, 2017 through June 30, 2018 reflect a 2.31 percent increase in the Consumer Price Index for All Urban Consumers during the 12-month period May 2016 to May 2017 (from a level of 262.074 in May 2016, as previously published in the **Federal Register** to 268.128 in May 2017). Adjustments to the national average payment rates for all lunches served under the National School Lunch Program, breakfasts served under the School Breakfast Program, and afterschool snacks served under the National School Lunch Program are rounded down to the nearest whole cent.

*Lunch Payment Levels—*Section 4 of the Richard B. Russell National School Lunch Act (42 U.S.C. 1753) provides general cash for food assistance payments to States to assist schools in purchasing food. The Richard B. Russell National School Lunch Act provides two different section 4 payment levels for lunches served under the National School Lunch Program. The lower payment level applies to lunches served by school food authorities in which less than 60 percent of the lunches served in the school lunch program during the second preceding school year were served free or at a reduced price. The higher payment level applies to lunches served by school food authorities in which 60 percent or more of the lunches served during the second preceding school year were served free or at a reduced price.

To supplement these section 4 payments, section 11 of the Richard B. Russell National School Lunch Act (42 U.S.C. 1759(a)) provides special cash assistance payments to aid schools in providing free and reduced price lunches. The section 11 National Average Payment Factor for each reduced price lunch served is set at 40 cents less than the factor for each free lunch.

As authorized under sections 8 and 11 of the Richard B. Russell National School Lunch Act (42 U.S.C. 1757 and 1759a), maximum reimbursement rates for each type of lunch are prescribed by the Department in this Notice. These maximum rates are to ensure equitable disbursement of Federal funds to school food authorities.

*Section 201 of the Healthy, Hunger-Free Kids Act of 2010—*Section 201 of the Healthy, Hunger-Free Kids Act of 2010 made significant changes to the Richard B. Russell National School Lunch Act. On January 3, 2014, the final rule entitled, “Certification of Compliance With Meal Requirements for the National School Lunch Program

Under the Healthy, Hunger-Free Kids Act of 2010” (79 FR 325), was published and provides eligible school food authorities with performance-based cash reimbursement in addition to the general and special cash assistance described above. The final rule requires that school food authorities be certified by the State agency as being in compliance with the updated meal pattern and nutrition standard requirements set forth in amendments to 7 CFR parts 210 and 220 on January 26, 2012, in the final rule entitled “Nutrition Standards in the National School Lunch and School Breakfast Programs” (77 FR 4088). Certified school food authorities are eligible to receive performance-based cash assistance for each reimbursable lunch served (an additional six cents per lunch available beginning October 1, 2012, and adjusted annually thereafter).

Afterschool Snack Payments in Afterschool Care Programs—Section 17A of the Richard B. Russell National School Lunch Act (42 U.S.C. 1766a) establishes National Average Payments for free, reduced price and paid afterschool snacks as part of the National School Lunch Program.

Breakfast Payment Factors—Section 4 of the Child Nutrition Act of 1966 (42 U.S.C. 1773) establishes National Average Payment Factors for free, reduced price, and paid breakfasts served under the School Breakfast Program and additional payments for free and reduced price breakfasts served in schools determined to be in “severe need” because they serve a high percentage of needy children.

Revised Payments

The following specific section 4, section 11, and section 17A National Average Payment Factors and maximum reimbursement rates for lunch, the afterschool snack rates, and the breakfast rates are in effect from July 1, 2017 through June 30, 2018. Due to a higher cost of living, the average payments and maximum reimbursements for Alaska, Puerto Rico and Hawaii are higher than those for all other States. The District of Columbia, Virgin Islands, and Guam use the figures specified for the contiguous States.

National School Lunch Program Payments

Section 4 National Average Payment Factors—In school food authorities that served less than 60 percent free and reduced price lunches in School Year (SY) 2015–16, the payments for meals served are: *Contiguous States*—paid rate—31 cents (1 cent increase from the SY 2016–17 level), free and reduced price rate—31 cents (1 cent increase), maximum rate—39 cents (1 cent increase); *Alaska*—paid rate—50 cents (1 cent increase), free and reduced price rate—50 cents (1 cent increase), maximum rate—61 cents (1 cent increase); *Hawaii and Puerto Rico*—paid rate—36 cents (1 cent increase), free and reduced price rate—36 cents (1 cent increase), maximum rate—45 cents (1 cent increase).

In school food authorities that served 60 percent or more free and reduced price lunches in School Year 2015–16, payments are: *Contiguous States*—paid rate—33 cents (1 cent increase from the SY 2016–17 level), free and reduced price rate—33 cents (1 cent increase), maximum rate—39 cents (1 cent increase); *Alaska*—paid rate—52 cents (1 cent increase), free and reduced price rate—52 cents (1 cent increase), maximum rate—61 cents (1 cent increase); *Hawaii and Puerto Rico*—paid rate—38 cents (1 cent increase), free and reduced price rate—38 cents (1 cent increase), maximum rate—45 cents (1 cent increase).

School food authorities certified to receive the performance-based cash assistance will receive an additional 6 cents (adjusted annually) added to the above amounts as part of their section 4 payments.

Section 11 National Average Payment Factors—*Contiguous States*—free lunch—292 cents (6 cents increase from the SY 2016–2017 level), reduced price lunch—252 cents (6 cents increase); *Alaska*—free lunch—474 cents (11 cents increase), reduced price lunch—434 cents (11 cents increase); *Hawaii and Puerto Rico*—free lunch—342 cents (8 cents increase), reduced price lunch—302 cents (8 cents increase).

Afterschool Snacks in Afterschool Care Programs—The payments are: *Contiguous States*—free snack—88 cents (2 cents increase from the SY 2016–2017 level), reduced price snack—44 cents (1

cent increase), paid snack—8 cents (1 cent increase); *Alaska*—free snack—144 cents (4 cents increase), reduced price snack—72 cents (2 cents increase), paid snack—13 cents (1 cent increase); *Hawaii and Puerto Rico*—free snack—104 cents (3 cents increase), reduced price snack—52 cents (2 cents increase), paid snack—9 cents (no change).

School Breakfast Program Payments

For schools “not in severe need” the payments are: *Contiguous States*—free breakfast—175 cents (4 cents increase from the SY 2016–2017 level), reduced price breakfast—145 cents (4 cents increase), paid breakfast—30 cents (1 cent increase); *Alaska*—free breakfast—279 cents (6 cents increase), reduced price breakfast—249 cents (6 cents increase), paid breakfast—45 cents (1 cent increase); *Hawaii and Puerto Rico*—free breakfast—203 cents (4 cents increase), reduced price breakfast—173 cents (4 cents increase), paid breakfast—34 cents (1 cent increase).

For schools in “severe need” the payments are: *Contiguous States*—free breakfast—209 cents (5 cents increase from the SY 2016–2017 level), reduced price breakfast—179 cents (5 cents increase), paid breakfast—30 cents (1 cent increase); *Alaska*—free breakfast—335 cents (8 cents increase), reduced price breakfast—305 cents (8 cents increase), paid breakfast—45 cents (1 cent increase); *Hawaii and Puerto Rico*—free breakfast—243 cents (5 cents increase), reduced price breakfast—213 cents (5 cents increase), paid breakfast—34 cents (1 cent increase).

Payment Chart

The following chart illustrates the lunch National Average Payment Factors with the sections 4 and 11 already combined to indicate the per lunch amount; the maximum lunch reimbursement rates; the reimbursement rates for afterschool snacks served in afterschool care programs; the breakfast National Average Payment Factors including “severe need” schools; and the milk reimbursement rate. All amounts are expressed in dollars or fractions thereof. The payment factors and reimbursement rates used for the District of Columbia, Virgin Islands, and Guam are those specified for the contiguous States.

SCHOOL PROGRAMS							
MEAL, SNACK AND MILK PAYMENTS TO STATES AND SCHOOL FOOD AUTHORITIES							
Expressed in Dollars or Fractions Thereof							
Effective from: July 1, 2017 - June 30, 2018							
NATIONAL SCHOOL LUNCH PROGRAM ¹		LESS THAN 60%	LESS THAN 60% + 6 cents ²	60% OR MORE	60% or MORE + 6 cents ²	MAXIMUM RATE	MAXIMUM RATE + 6 cents ²
CONTIGUOUS STATES	PAID	0.31	0.37	0.33	0.39	0.39	0.45
	REDUCED PRICE	2.83	2.89	2.85	2.91	3.00	3.06
	FREE	3.23	3.29	3.25	3.31	3.40	3.46
ALASKA	PAID	0.50	0.56	0.52	0.58	0.61	0.67
	REDUCED PRICE	4.84	4.90	4.86	4.92	5.09	5.15
	FREE	5.24	5.30	5.26	5.32	5.49	5.55
HAWAII and PUERTO RICO	PAID	0.36	0.42	0.38	0.44	0.45	0.51
	REDUCED PRICE	3.38	3.44	3.40	3.46	3.57	3.63
	FREE	3.78	3.84	3.80	3.86	3.97	4.03
SCHOOL BREAKFAST PROGRAM				NON-SEVERE NEED		SEVERE NEED	
CONTIGUOUS STATES		PAID		0.30		0.30	
		REDUCED PRICE		1.45		1.79	
		FREE		1.75		2.09	
ALASKA		PAID		0.45		0.45	
		REDUCED PRICE		2.49		3.05	
		FREE		2.79		3.35	
HAWAII and PUERTO RICO		PAID		0.34		0.34	
		REDUCED PRICE		1.73		2.13	
		FREE		2.03		2.43	
SPECIAL MILK PROGRAM				ALL MILK	PAID MILK	FREE MILK	
PRICING PROGRAMS WITHOUT FREE OPTION				0.2075	N/A	N/A	
PRICING PROGRAMS WITH FREE OPTION				N/A	0.2075	Average Cost Per 1/2 Pint of Milk	
NONPRICING PROGRAMS				0.2075	N/A	N/A	
AFTERSCHOOL SNACKS SERVED IN AFTERSCHOOL CARE PROGRAMS							
CONTIGUOUS STATES			PAID			0.08	
			REDUCED PRICE			0.44	
			FREE			0.88	
ALASKA			PAID			0.13	
			REDUCED PRICE			0.72	
			FREE			1.44	
HAWAII and PUERTO RICO			PAID			0.09	
			REDUCED PRICE			0.52	
			FREE			1.04	

¹ Payment listed for Free and Reduced Price Lunches include both section 4 and section 11 funds

² Performance-based cash reimbursement (adjusted annually for inflation)

no new recordkeeping or reporting requirements have been included that are subject to approval from the Office of Management and Budget.

This notice has been determined to be not significant and was not reviewed by the Office of Management and Budget in conformance with Executive Order 12866.

National School Lunch, School Breakfast, and Special Milk Programs are listed in the Catalog of Federal Domestic Assistance under No. 10.555, No. 10.553, and No. 10.556, respectively, and are subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials.

Authority: Sections 4, 8, 11, and 17A of the Richard B. Russell National School Lunch Act, as amended, (42 U.S.C. 1753, 1757, 1759a, 1766a) and sections 3 and 4(b) of the Child Nutrition Act, as amended, (42 U.S.C. 1772 and 42 U.S.C. 1773(b)).

Dated: July 13, 2017.

Jessica Shahin,

Acting Administrator, Food and Nutrition Service.

[FR Doc. 2017-15956 Filed 7-27-17; 8:45 am]

BILLING CODE 3410-30-P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection

Activities: Proposed Collection; Comment Request—Supplemental Nutrition Assistance Program Education (SNAP-Ed) Toolkit Intervention Submission Form and Scoring Tool

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on a proposed information collection, which will use two new forms.

The purpose of the SNAP-Ed Toolkit Intervention Submission Form and Scoring Tool is to provide a uniform and transparent method for submission, review, and scoring of nutrition education, physical activity promotion, and obesity prevention interventions for possible inclusion in the *SNAP-Ed Strategies and Interventions: An Obesity Prevention Toolkit for States* (Toolkit). The Toolkit was developed to assist State agencies in locating evidence-based interventions for their implementation of SNAP-Ed

programming. The Food and Nutrition Act of 2008, as amended (The Act) § 28(c)(3)(A) requires that States use evidence-based interventions. These forms will allow FNS to increase the selection of interventions available in the Toolkit, increase innovation in service delivery using interventions which reflect up-to-date research, and respond to intervention developer requests to be included in the Toolkit.

DATES: Written comments must be submitted on or before September 26, 2017.

ADDRESSES: 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 has practical utility; (b) the accuracy of the agency's estimate of the burden hours, including the validity of the methodology and assumptions that were used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical or other technological collection techniques or other forms of information technology.

Comments may be sent to Lisa Mays, State Administration Branch, Program Accountability and Administration Division, Supplemental Nutrition Assistance Program, U.S. Department of Agriculture, Food and Nutrition Service, 3101 Park Center Drive, Room 821, Alexandria, VA 22302. Comments may also be submitted via fax to the attention of Lisa Mays at 703-457-7762, or via email to SNAP-Ed@fns.usda.gov. Comments will also be accepted through the Federal eRulemaking Portal. Go to <http://www.regulations.gov> and follow the online instructions for submitting comments electronically.

All written comments will be open for public inspection at the office of the Food and Nutrition Service during regular business hours (8:30 a.m. to 5:00 p.m. Monday through Friday) at 3101 Park Center Drive, Room 821, Alexandria, Virginia 22302.

All responses to this notice will be summarized and included in the request for the Office of Management and Budget (OMB) approval. All comments will also be a matter of public record.

CONTACT FOR FURTHER INFORMATION:

Requests for additional information should be directed to Lisa Mays at SNAP-Ed@fns.usda.gov.

SUPPLEMENTARY INFORMATION:

Title: SNAP Ed Toolkit Intervention Scoring Tool and Submission Form.

OMB Number: 0584-NEW.

Form Numbers: FNS-885 and FNS-886.

Expiration Date: TBD.

Type of Request: New information collection.

Abstract: SNAP-Ed State and Implementing agencies are able to identify and choose evidence-based interventions using the Toolkit. The Toolkit was developed collaboratively by FNS National and Regional Office SNAP-Ed staff, the National Collaborative on Childhood Obesity Reduction (NCCOR), and the Association of SNAP Nutrition Education Administrators (ASNNA). Currently, more than 80 interventions are available in the Toolkit (<https://snapedtoolkit.org/>). This new data collection for additional interventions to be reviewed for inclusion in the Toolkit is necessary to:

- Increase the selection available to agencies to allow them to find interventions that fit their specific needs.
- Increase innovation in service delivery by encouraging adoption of interventions which reflect the most up-to-date research of nutrition education, physical activity, and obesity prevention behavior change.
- Allow FNS to respond to requests by intervention developers to be included in the Toolkit with a clear and transparent review process and criteria for inclusion.

The Food and Nutrition Act of 2008, as amended (The Act) § 28(c)(3)(A) states that State agencies “may use funds provided under this section for any evidence-based allowable use of funds” including “(i) individual and group-based nutrition education, health promotion, and intervention strategies”. 7 CFR 272.2(2)(d) also states “SNAP-Ed activities must include evidence-based activities using one or more of these approaches: Individual or group-based nutrition education, health promotion, and intervention strategies; comprehensive, multi-level interventions at multiple complementary organizational and institutional levels; community and public health approaches to improve nutrition”. The Intervention Submission Form (FNS 886) and Scoring Tool (FNS 885) allows for interventions to be assessed to determine if they are both evidence-based and use one of the approaches described.

The Intervention Submission Form will be used by intervention developers (submitters) to provide information about the intervention they are submitting for inclusion in the Toolkit. Information requested includes

intervention materials, how they have been and will be used, and the evidence base which illustrates their effectiveness. Information is collected through a combination of multiple-choice boxes and text response areas.

Submitters will be members of State or Implementing agencies, researchers from academic institutions and Federal agencies, such as the Economic Research Service (ERS), and non-profit or private sector nutrition education and physical activity intervention developers.

Submitters will be able to download, complete and submit the form at any time, although there will be an annual deadline for submission for the associated year's review. Download and submission will be through the SNAP-Ed Connection Web site (<https://snaped.fns.usda.gov/>). Completion is voluntary.

Submission Forms and attachments will be collected by FNS National Office SNAP-Ed staff and distributed to intervention reviewers (reviewers), who will use the Scoring Tool to help them determine if the intervention should be included in the Toolkit. The Scoring Tool rates the intervention according to the quality of materials, usefulness for SNAP-Ed, and effectiveness as demonstrated by the evidence base provided. Reviewers will be directly emailed the Intervention Scoring Tool. Numerical scores will be entered by reviewers as well as qualitative responses which clarify why an intervention was or was not included in the Toolkit. Information is collected through a combination of numerical and text entry fields.

Reviewers will be FNS National and Regional Office SNAP-Ed staff, nutrition program staff from other Federal agencies, such as Centers for Disease Control and Prevention (CDC), researchers from academic institutions, and SNAP-Ed State and Implementing agency staff.

The review period will occur annually, with reviewers completing the Scoring Tool and discussing inclusion in the Toolkit. Participation as a reviewer is voluntary, with completion of the Scoring Tool a mandatory component of review participation.

Affected Public: 8 State Agencies which operate the SNAP-Ed program and 82 local program operators (Business-for-not-for-profit) such as universities and non-profit organizations. Intervention developers may be SNAP-Ed State Agencies or local program operators, academic institutions not associated with SNAP-Ed, non-profit organizations, and private organizations who voluntarily complete the Intervention Submission Form. Members of FNS SNAP-Ed staff, federal employees from agencies such as CDC and NIH, as well as NCCOR or ASNNA members who may be employees of State Agencies or local program operators may voluntarily review interventions using the Intervention Scoring Tool.

Estimated Number of Respondents: 90.

Estimated Average Number of Responses per Respondent: 1.24242.

Estimated Total Annual Responses: 123.

Estimated Average Hours per Response: 3.46341.

Estimated Total Annual Burden Hours (Reporting Only): 426.

Estimated Total Annual Burden on Respondents: The estimated total reporting burden inventory for this collection is 400 hours. The Intervention Submission Form is expected to be completed once annually by 5 State Agencies and 52 local program operators (business-for-not-for-profit) for approximately 57 total annual responses annually. This form takes approximately 4 hours per respondent to complete for a total of 228 burden hours of reporting annually for this form. 20 hours of this burden will be applied to State Agencies while 208 hours will be applied to local program operators (business-for-not-for-profit). This burden estimate was developed by averaging the time provided by two pilot testers of the form, who used interventions currently available in the Toolkit to test the Intervention Submission Form. The Intervention Scoring Tool is expected to be completed twice by a predicted 22 local program operators (business-for-not-for-profit) and 3 State Agencies for a total 66 annual responses. This form takes 3 hours per respondent to complete, for a total of 198 reporting hours annually. 18 hours of this burden will be applied to State Agencies and 180 hours will be applied to local program operators (business-for-not-for-profit). This burden estimate was developed by averaging the time provided by three pilot testers of the form, who used information provided by the pilot testers of the Intervention Submission form to test the Intervention Scoring Tool.

There are no recordkeeping burden activities for these forms.

TABLE A.12-3—SUMMARY REPORTING BURDEN

Affected public	Respondent type	Form	Estimated number of respondents	Number of responses per respondent	Total annual responses	Estimated total hours per response	Estimated total burden
State, Local or Tribal Agencies	Intervention Submitters	Intervention Submission Form (FNS 886).	5	1	5	4	20
State, Local, or Tribal Agencies.	Intervention Reviewers ..	Scoring Tool (FNS 885)	3	2	6	3	18
States Agency Sub-Total			8	1.375	11	3.4545	38
Business-for-not-for-profit	Intervention Submitters	Intervention Submission Form (FNS 886).	52	1	52	4	208
Business-for-not-for-profit	Intervention Reviewers ..	Scoring Tool (FNS 885)	30	2	60	3	180
Business Sub-Total			82	1.365	112	3.46428	388
Grand Total Reporting for Each Affected Public.			90		123		426

Dated: July 20, 2017.

Jessica Shahin,

Acting Administrator, Food and Nutrition Service.

[FR Doc. 2017-15899 Filed 7-27-17; 8:45 am]

BILLING CODE 3410-30-P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Food Distribution Program: Value of Donated Foods From July 1, 2017 through June 30, 2018

AGENCY: Food and Nutrition Service, USDA.

ACTION: Notice.

SUMMARY: This notice announces the national average value of donated foods or, where applicable, cash in lieu of donated foods, to be provided in school year 2018 (July 1, 2017 through June 30, 2018) for each lunch served by schools participating in the National School Lunch Program (NSLP), and for each lunch and supper served by institutions participating in the Child and Adult Care Food Program (CACFP).

DATES: *Effective date:* July 1, 2017.

FOR FURTHER INFORMATION CONTACT: Polly Fairfield, Program Analyst, Policy Branch, Food Distribution Division, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Alexandria, Virginia 22302-1594, or telephone (703) 305-2680.

SUPPLEMENTARY INFORMATION: These programs are listed in the Catalog of Federal Domestic Assistance under Nos. 10.555 and 10.558 and are subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials.

This notice imposes no new reporting or recordkeeping provisions that are subject to Office of Management and Budget review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). This action is not a rule as defined by the Regulatory Flexibility Act (5 U.S.C. 601-612) and thus is exempt from the provisions of that Act. This notice was not reviewed by the Office of Management and Budget under Executive Order 12866.

National Average Minimum Value of Donated Foods for the Period July 1, 2017 Through June 30, 2018

This notice implements mandatory provisions of sections 6(c) and 17(h)(1)(B) of the Richard B. Russell National School Lunch Act (the Act) (42 U.S.C. 1755(c) and 1766(h)(1)(B)).

Section 6(c)(1)(A) of the Act establishes the national average value of donated food assistance to be given to States for each lunch served in the NSLP at 11.00 cents per meal. Pursuant to section 6(c)(1)(B), this amount is subject to annual adjustments on July 1 of each year to reflect changes in a three-month average value of the Producer Price Index for Foods Used in Schools and Institutions for March, April, and May each year (Price Index). Section 17(h)(1)(B) of the Act provides that the same value of donated foods (or cash in lieu of donated foods) for school lunches shall also be established for lunches and suppers served in the CACFP. Notice is hereby given that the national average minimum value of donated foods, or cash in lieu thereof, per lunch under the NSLP (7 CFR part 210) and per lunch and supper under the CACFP (7 CFR part 226) shall be 23.25 cents for the period July 1, 2017 through June 30, 2018.

The Price Index is computed using five major food components in the Bureau of Labor Statistics Producer Price Index (cereal and bakery products; meats, poultry and fish; dairy; processed fruits and vegetables; and fats and oils). Each component is weighted using the relative weight as determined by the Bureau of Labor Statistics. The value of food assistance is adjusted each July 1 by the annual percentage change in a three-month average value of the Price Index for March, April, and May each year. The three-month average of the Price Index increased by 0.98 percent from 201.77 for March, April, and May of 2016, as previously published in the **Federal Register**, to 203.76 for the same three months in 2017. When computed on the basis of unrounded data and rounded to the nearest one-quarter cent, the resulting national average for the period July 1, 2017 through June 30, 2018 will be 23.25 cents per meal. This is an increase of one quarter of a cent from the school year 2017 (July 1, 2016 through June 30, 2017) rate.

Authority: Sections 6(c)(1)(A) and (B), 6(e)(1), and 17(h)(1)(B) of the Richard B. Russell National School Lunch Act (42 U.S.C. 1755(c)(1)(A) and (B) and (e)(1), and 1766(h)(1)(B)).

Dated: July 13, 2017.

Jessica Shahin,

Acting Administrator, Food and Nutrition Service.

[FR Doc. 2017-15971 Filed 7-27-17; 8:45 am]

BILLING CODE 3410-30-P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Louisiana Advisory Committee To Discuss Civil Rights Topics in the State

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 Louisiana Advisory Committee (Committee) will hold a meeting on Tuesday, August 8, 2017, at 2:00 p.m. Central for the purpose of a discussion on civil rights topics affecting the state.

DATES: The meeting will be held on Tuesday, August 8, 2017, at 2:00 p.m. CDT.

PUBLIC CALL INFORMATION: Dial: 866-791-6248, Conference ID: 3065952.

FOR FURTHER INFORMATION CONTACT: David Barreras, DFO, at dbarreras@usccr.gov or 312-353-8311.

SUPPLEMENTARY INFORMATION: Members of the public can listen to the discussion. This meeting is available to the public through the following toll-free call-in number: 866-791-6248, conference ID: 3065952. Any interested member of the public may call this number and listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur 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 1-800-977-8339 and providing the Service with the conference call number and conference ID number.

Members of the public are also 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 Midwestern Regional Office, U.S. Commission on Civil Rights, 55 W. Monroe St., Suite 410, Chicago, IL 60615. They may also be faxed to the

Commission at (312) 353-8324, or emailed to Carolyn Allen at callen@usccr.gov. Persons who desire additional information may contact the Midwestern Regional Office at (312) 353-8311.

Records generated from this meeting may be inspected and reproduced at the Midwestern Regional Office, as they become available, both before and after the meeting. Records of the meeting will be available via www.facadatabase.gov under the Commission on Civil Rights, Louisiana Advisory Committee link (<https://database.faca.gov/committee/committee.aspx?cid=251&aid=17>). Persons interested in the work of this Committee are directed to the Commission's Web site, <http://www.usccr.gov>, or may contact the Midwestern Regional Office at the above email or street address.

Agenda

Welcome and Roll Call
Civil Rights Topics in Louisiana
Next Steps
Public Comment
Adjournment

Dated: July 24, 2017.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2017-15893 Filed 7-27-17; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-583-850]

Certain Oil Country Tubular Goods From Taiwan: Notice of Court Decision Not in Harmony With Final Determination of Sales at Less Than Fair Value, Notice of Amended Final Determination and Revocation of Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On July 12, 2017, the United States Court of International Trade (CIT) entered its final judgment sustaining the final results of remand redetermination pursuant to court order by the Department of Commerce (Department) pertaining to the less-than-fair-value (LTFV) investigation of certain oil country tubular goods (OCTG) from Taiwan. The Department is notifying the public that the final judgment in this case is not in harmony with the Department's final determination in the LTFV investigation of OCTG from Taiwan. Pursuant to the CIT's final judgment, both mandatory respondents

in the LTFV investigation of OCTG from Taiwan have received weighted-average dumping margins of zero and, therefore, the Department is hereby revoking this order.

DATES: Applicable July 22, 2017.

FOR FURTHER INFORMATION CONTACT:

Hermes Pinilla, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482-3477.

SUPPLEMENTARY INFORMATION:

Background

On August 8, 2014, the Department published the *LTFV Final* in this proceeding.¹ The Department reached an affirmative determination that certain OCTG was being, or likely to be, sold at less than fair value, for mandatory respondent, Tension Steel Industries Co., Ltd. (Tension Steel). Tension Steel appealed the *LTFV Final* to the CIT, and on May 16, 2016, the CIT remanded the final determination.² Specifically, the CIT remanded the *LTFV Final* directing the Department to grant all of Tension Steel's claimed rebate adjustments, including where the conditions of the rebate were unknown to the customer at the time of sale.³

On July 15, 2016, the Department issued its final results of redetermination pursuant to remand in accordance with the CIT's order.⁴ On remand, the Department, under respectful protest,⁵ granted all of Tension Steel's reported rebates and recalculated the margin for Tension Steel accordingly. On July 12, 2017, the CIT sustained the Department's *Remand Order*.⁶ Thus, the effective date of this notice is July 22, 2017.

¹ See *Certain Oil Country Tubular Goods from Taiwan: Final Determination of Sales at Less Than Fair Value*, 79 FR 41979 (July 18, 2014); amended in *Certain Oil Country Tubular Goods from Taiwan: Amended Final Determination of Sales at Less Than Fair Value*, 79 FR 46403 (August 8, 2014) (*LTFV Final*).

² See *Tension Steel Industries Co., Ltd. v. United States*, 179 F. Supp. 3d 1185 (CIT 2016) (*Remand Order*).

³ See *Remand Order*, 179 F. Supp. 3d at 1190-91.

⁴ See Final Results of Redetermination Pursuant to Remand, *Tension Steel Industries Co., Ltd. v. United States*, Consol. Court No. 14-00218, Slip Op. 16-51, dated July 15, 2016 (*Final Redetermination*). See also, <http://enforcement.trade.gov/remands/16-51.pdf>.

⁵ See *Viraj Group, Ltd. v. United States*, 343 F.3d 1371 (Fed. Cir. 2003).

⁶ See *Tension Steel Industries Co., Ltd. v. United States*, Slip Op. 17-84, Consol. Court No. 14-00218 (CIT July 12, 2017) (*Final Remand Order*).

Timken Notice

In its decision in *Timken*,⁷ as clarified by *Diamond Sawblades*,⁸ the Court of Appeals for the Federal Circuit (Federal Circuit) held that, pursuant to section 516A of the Tariff Act of 1930, as amended (the Act), the Department must publish a notice of court decision that is not "in harmony" with a Department determination and must suspend liquidation of entries pending a "conclusive" court decision.⁹ The CIT's July 12, 2017, judgment constitutes a final decision of that court that is not in harmony with the Department's original affirmative determination in the *LTFV Final*. Thus, this notice is published in fulfillment of the publication requirements of *Timken* and section 516A of the Act.

Accordingly, the Department intends to issue instructions to U.S. Customs and Border Protection to suspend liquidation of all unliquidated entries of subject merchandise from Taiwan which are entered, or withdrawn from warehouse, for consumption on or after July 22, 2017, which is ten days after the court's decision in accordance with section 516A of the Act. The company-specific cash deposit rate will be zero percent. Pursuant to *Timken*, *Diamond Sawblades*, and *Hosiden Corporation v. United States*, 861 F. Supp. 115 (Fed. Cir. 1994), the suspension of liquidation on all entries of OCTG from Taiwan entered, or withdrawn from warehouse, for consumption on or after July 22, 2017, that remain unliquidated, will be suspended during the pendency of the appeals process so that they may be liquidated in accordance with a "final and conclusive" court decision.

Amended Final Determination

Because there is now a final court decision, the Department is amending the *LTFV Final* with respect to Tension Steel. The revised weighted-average dumping margin for Tension Steel for the period July 1, 2012, through June 30, 2013, is as follows:

Exporter or producer	Weighted-average dumping margin (percent)
Tension Steel Industries Co., Ltd	0.00

⁷ See *Timken Co. v. United States*, 893 F.2d 337 (Fed. Cir. 1990) (*Timken*).

⁸ See *Diamond Sawblades Mfrs. Coalition v. United States*, 626 F.3d 1374 (Fed. Cir. 2010) (*Diamond Sawblades*).

⁹ See Sections 516A(c) and (e) of the Act.

Revocation of the Order

Pursuant to section 735(c)(2) of the Act, “the investigation shall be terminated upon publication of that negative determination” and the Department shall “terminate the suspension of liquidation” and “release any bond or other security and refund any cash deposit.”¹⁰ As a result of this amended final determination, the Department is hereby revoking the antidumping duty order and releasing any bonds or other security and refunding cash deposits with respect to Tension Steel.

Pursuant to the Federal Circuit’s decision in *Diamond Sawblades*¹¹ and the CIT’s decision affirming the Department’s remand redetermination, the Department is revoking the antidumping duty order on OCTG from Taiwan because the revised weighted-average dumping margin for Tension Steel is now zero, and because the Department also calculated a zero margin for the only other mandatory respondent in the underlying investigation. As a result of this revocation, the Department will not initiate any new administrative reviews of this antidumping duty Order.¹²

Although section 735(c)(2)(A) of the Act instructs the Department to terminate suspension of liquidation, here, because suspension of liquidation must continue during the pendency of the appeals process (in accordance with *Timken* and as discussed above), we will continue to instruct CBP at this time to (A) continue suspension at a cash deposit rate of zero percent until instructed otherwise; and (B) release any bond or other security, and refund any cash deposit made pursuant to *OCTG From Taiwan: Antidumping Duty Order*.¹³ In the event that the court’s ruling in the *Final Remand Order* is not appealed, or appealed and upheld by the CAFC, the Department will instruct CBP to terminate the suspension of

liquidation and to liquidate those entries of subject merchandise without regard to antidumping duties. Notwithstanding the continued suspension described above, the antidumping duty order on OCTG from Taiwan is hereby revoked, also described above.

Notification to Interested Parties

This notice serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of the APO is a violation subject to sanction.

This notice is issued and published in accordance with sections 516A(e)(1), 751(a)(1) and 777(i)(1) of the Act.

Dated: July 24, 2017.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2017–15944 Filed 7–27–17; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–857]

Certain Oil Country Tubular Goods From India: Notice of Correction to Amended Final Determination and Amendment of Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

FOR FURTHER INFORMATION CONTACT:

Andrew Huston, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–4261.

SUPPLEMENTARY INFORMATION:

Background

In the *Final Determination*, the Department determined that GVN Fuels Limited, Maharashtra Seamless Limited, and Jindal Pipes Limited are affiliated, pursuant to section 771(33)(F) of the Tariff Act of 1930, as amended (the Act),

and should be collapsed and treated as a single entity, pursuant to 19 CFR 351.401(f).¹

On March 16, 2017, the United States Court of International Trade (CIT) entered final judgment sustaining the final results of remand redetermination pursuant to court order by the Department of Commerce (Department) pertaining to the less-than-fair-value investigation of certain oil country tubular goods (OCTG) from India.² On April 12, 2017, the Department published the *Amended Final Determination* on OCTG from India.³ On June 20, 2017, the Department published the *Amended Order*.⁴ In both the *Amended Final Determination* and *Amended Order*, the Department inadvertently omitted a statement to explain that, consistent with the *Final Determination*,⁵ GVN Fuels Limited, Maharashtra Seamless Limited, and Jindal Pipes Limited should be treated as a single entity.

Correction

We are correcting the *Amended Final Determination* and *Amended Order* to clarify that GVN Fuels Limited, Maharashtra Seamless Limited, and Jindal Pipes Limited should be treated as a single entity (collectively, GVN or the GVN single entity). The sections of the *Amended Final Determination* and *Amended Order* explaining the suspension of liquidation and listing the weighted-average antidumping duty margins and cash deposit rates should have appeared as provided below.

Correction to the Amended Final Determination

Amended Final Determination

Because there is now a final court decision, the Department is amending the *Final Determination* with respect to the GVN single entity (comprised of

¹ See *Final Determination of Sales at Less Than Fair Value and Final Negative Determination of Critical Circumstances: Certain Oil Country Tubular Goods from India*, 79 FR 41981, 41982 (July 18, 2014) (*Final Determination*), and accompanying issues and decision memorandum (IDM) at Comment 9.

² See *United States Steel Corporation et al. v. United States*, Slip Op. 17–28, Consolidated Court No. 14–00263 (CIT 2017).

³ See *Certain Oil Country Tubular Goods from India: Notice of Court Decision Not in Harmony With Final Determination of Sales at Less Than Fair Value and Final Negative Determination of Critical Circumstances and Notice of Amended Final Determination*, 82 FR 17631 (April 12, 2017) (*Amended Final Determination*).

⁴ See *Certain Oil Country Tubular Goods from India: Amendment of Antidumping Duty Order*, 82 FR 28045 (June 20, 2017) (*Amended Order*).

⁵ See *Final Determination*, 79 FR at 41982, and accompanying issues and decision memorandum (IDM) at Comment 9.

¹⁰ See sections 735(c)(2)(A) and (B) of the Act.

¹¹ See *Diamond Sawblades Mfrs. Coalition v. United States*, 626 F.3d 1374 (Fed. Cir. 2010) (*Diamond Sawblades*).

¹² Currently there are no unfinished or ongoing administrative reviews of this order. Further, we rescinded the 2015/2016 administrative review on March 1, 2017, and this was the last administrative review completed in this proceeding. See *Certain Oil Country Tubular Goods from Taiwan: Rescission of Antidumping Duty Administrative Review; 2015–2016*, 82 FR 12197 (March 1, 2017).

¹³ See *Certain Oil Country Tubular Goods from India, the Republic of Korea, Taiwan, the Republic of Turkey, and the Socialist Republic of Vietnam: Antidumping Duty Orders; and Certain Oil Country Tubular Goods from the Socialist Republic of Vietnam: Amended Final Determination of Sales at Less Than Fair Value*, 79 FR 53691 (September 10, 2014) (OCTG From Taiwan: Antidumping Duty Order).

GVN Fuels Limited, Maharashtra Seamless Limited and Jindal Pipes

Limited)⁶ and Jindal SAW, Limited.
The revised weighted-average dumping

margins for the period July 1, 2012, through June 30, 2013, are as follows:

Exporter or producer	Estimated weighted-average dumping margins (percent)	Cash deposit rate percent (percent) ⁷
GVN Fuels Limited, Maharashtra Seamless Limited and Jindal Pipes Limited (collectively, GVN or GVN single entity)	* 1.07	0.00
Jindal SAW, Limited	11.24	0.00
All Others	5.79	0.00

*(de minimis).

Correction to the Amended Order

Amendment of the Order on OCTG From India

The period to appeal the Court of International Trade's decision has passed, and a final and conclusive court decision has been reached in this case. Therefore, the Department is amending the antidumping duty order⁸ on OCTG from India to exclude from the order subject merchandise produced and exported by the GVN single entity (comprised of GVN Fuels Limited, Maharashtra Seamless Limited and Jindal Pipes Limited)⁹ because the revised weighted-average dumping margin for the GVN single entity is *de minimis*. This exclusion does not apply to merchandise produced by the GVN single entity and exported by any other company (outside the GVN single entity) or merchandise produced by any other company and exported by the GVN single entity. Resellers of merchandise produced by the GVN single entity, are also not entitled to this exclusion.

Continuation of Suspension of Liquidation, In Part

In accordance with section 735(c)(1)(B) of the Act, the Department has instructed CBP to continue to suspend liquidation on all relevant entries of OCTG from India.¹⁰ These instructions suspending liquidation will remain in effect until further notice. However, because the estimated weighted-average dumping margin for merchandise produced and exported by the GVN single entity is *de minimis*, the Department is directing U.S. Customs and Border Protection to liquidate all

entries produced and exported by the GVN single entity currently suspended without regard to antidumping duties, and to not to suspend liquidation of entries of subject merchandise where the GVN single entity acted as both the producer and exporter. Entries of subject merchandise exported to the United States by any other producer and exporter combination involving the GVN single entity are not entitled to this exclusion from suspension of liquidation and are subject to the cash deposit rate for the all-others entity.

This correction to the *Amended Final Determination and Amended Order* is issued and published in accordance with sections 516A(e)(1), 735(d), 736(a), and 777(i) of the Act of the Act.

Dated: July 24, 2017.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2017-15943 Filed 7-27-17; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-898]

Chlorinated Isocyanurates From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review; 2015-2016

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

Vietnam: Amended Final Determination of Sales at Less Than Fair Value, 79 FR 53691 (September 10, 2014) (Orders).

⁹ *Final Determination Notice*, 79 FR at 41982, and accompanying IDM at Comment 9.

¹⁰ See Orders at 53692; see also Message No. 4262301, dated September 19, 2017, and Message No. 7130310, dated May 10, 2017.

¹ For a complete description of the Scope of the Order, see Memorandum from Gary Taverman,

SUMMARY: The Department of Commerce (the Department) is conducting an administrative review of the antidumping duty order on chlorinated isocyanurates (chlorinated isos) from the People's Republic of China (PRC). The period of review (POR) is June 1, 2015, through May 31, 2016. This administrative review covers three producers/exporters: (1) Heze Huayi Chemical Co. Ltd. (Heze Huayi); (2) Hebei Jiheng Chemical Co. Ltd. (Jiheng); and (3) Juancheng Kangtai Chemical Co. Ltd. (Kangtai). We preliminarily determine that Heze Huayi and Kangtai have demonstrated their eligibility for a separate rate, and have made sales in the United States at prices below normal value (NV). We also preliminarily determine that Jiheng has not demonstrated its eligibility for a separate rate. Interested parties are invited to comment on these preliminary results.

DATES: July 28, 2017.

FOR FURTHER INFORMATION CONTACT: Sean Carey, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482-3964.

SUPPLEMENTARY INFORMATION:

Scope of the Order

The products covered by the order are chlorinated isos, which are derivatives of cyanuric acid, described as chlorinated s-triazine triones.¹ Chlorinated isos are currently classifiable under subheadings 2933.69.6015, 2933.69.6021, 2933.69.6050, 3808.40.50, 3808.50.40

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Ronald K. Lorentzen, Acting Assistant Secretary for Enforcement and Compliance, "Decision Memorandum for the Preliminary Results of the 2015-2016 Antidumping Duty Administrative Review: Chlorinated Isocyanurates from the People's Republic of China," dated concurrently with this notice (Preliminary Decision Memorandum).

⁶ *Final Determination Notice*, 79 FR at 41982, and accompanying IDM at Comment 9.

⁷ Cash deposit rates are lower than estimated weighted-average dumping margins due to offsets for export subsidies.

⁸ See *Certain Oil Country Tubular Goods From India, the Republic of Korea, Taiwan, the Republic of Turkey, and the Socialist Republic of Vietnam: Antidumping Duty Orders; and Certain Oil Country Tubular Goods From the Socialist Republic of*

and 3808.94.5000 of the Harmonized Tariff Schedule of the United States (HTSUS). The HTSUS subheadings are provided for convenience and customs purposes only; the written product description of the scope of the order is dispositive.

Methodology

The Department is conducting this administrative review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). Export and constructed export prices have been calculated in accordance with section 772 of the Act. Because the PRC is a non-market economy within the meaning of section 771(18) of the Act, normal value has been calculated in accordance with section 773(c) of the Act. For a full description of the methodology underlying our conclusions, see the Preliminary Decision Memorandum, which is hereby adopted by this notice. A list of the topics included in the Preliminary Decision Memorandum is included as an appendix to this notice.

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 it is available to all parties in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum is available at <http://enforcement.trade.gov/frn/>. The signed Preliminary Decision Memorandum and the electronic version of the Preliminary Decision Memorandum are identical in content.

Verification

As provided in sections 782(i)(3)(A)–(B) of the Act, we intend to verify the information upon which we will rely in determining our final results of review with respect to Kangtai.

Preliminary Results of Review

The Department preliminarily finds that Jiheng did not respond to the Department's questionnaire even though it timely submitted a separate rate certification. As such, we preliminarily determine that Jiheng is part of the PRC-wide entity.² For the companies' subject

to this review that have established their eligibility for a separate rate, the Department preliminarily determines that the following weighted-average dumping margins exist for the period of June 1, 2015, through May 31, 2016:

Exporter	Weight-average dumping margin percentage
Heze Huayi Chemical Co. Ltd	16.06
Juancheng Kangtai Chemical Co. Ltd	24.82

Disclosure and Public Comment

The Department intends to disclose the calculations for these preliminary results within five days of the date of publication of this notice, in accordance with 19 CFR 351.224(b).

Because, as noted above, the Department intends to verify the information submitted by Kangtai upon which we will rely in making our final determination. Interested parties may submit written comments in the form of case briefs within one week after the issuance of the last verification report and rebuttal comments in the form of rebuttal briefs within five days after the time limit for filing case brief.³ Parties who submit case briefs or rebuttal briefs in this proceeding are requested to submit with each with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.⁴

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Enforcement and Compliance, within 30 days of the date of publication of this notice.⁵ 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 those raised in the respective case and rebuttal 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

to change as a result of this review. See *Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings*, 78 FR 65963, 65969–70 (November 4, 2013).

³ See 19 CFR 351.309(c)(1)(ii).

⁴ See 19 CFR 351.309(c)–(d); see also 19 CFR 351.303 (for general filing requirements).

⁵ See 19 CFR 351.310(c).

Constitution Avenue NW., Washington, DC 20230.⁶ Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

All submissions, with limited exceptions, must be filed electronically using ACCESS. An electronically filed document must be received successfully in its entirety by 5 p.m. Eastern Time (ET) on the due date. Documents excepted from the electronic submission requirements must be filed manually (e.g., in paper form) with the APO/ Dockets Unit in Room 18022 and stamped with the date and time of receipt by 5 p.m. ET on the due date.

The Department intends to issue the final results of this administrative review, which will include the results of verification and our analysis of all issues raised in the case briefs, within 120 days of publication of these preliminary results in the **Federal Register**, unless extended, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rates

Upon issuing the final results of this review, the Department shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review.⁷ The Department intends to issue assessment instructions to CBP 15 days after the date of publication of the final results of this review.

In accordance with 19 CFR 351.212(b)(1), we are calculating importer- (or customer-) specific assessment rates for the merchandise subject to this review. For any individually examined respondent whose weighted-average dumping margin is above *de minimis* (i.e., 0.50 percent), the Department will calculate importer-specific assessment rates on the basis of the ratio of the total amount of dumping calculated for the importer's examined sales and the total entered value of sales.⁸ We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review when the importer-specific assessment rate is above *de minimis*. Where either the respondent's weighted-average dumping margin is zero or *de minimis*, or an importer-specific assessment rate is zero or *de minimis*, we will instruct CBP to liquidate the

⁶ See 19 CFR 351.310(d).

⁷ See 19 CFR 351.212(b)(1).

⁸ See *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification*, 77 FR 8101 (February 14, 2012).

² Because no interested party requested a review of the PRC-wide entity and the Department no longer considers the PRC-wide entity as an exporter conditionally subject to administrative reviews, we did not conduct a review of the PRC-wide entity. Thus, the rate for the PRC-wide entity is not subject

appropriate entries without regard to antidumping duties.

For entries that were not reported in the U.S. sales database submitted by an exporter individually examined during this review, the Department will instruct CBP to liquidate such entries at the PRC-wide rate. Additionally, if the Department determines that an exporter under review had no shipments of the subject merchandise, any suspended entries that entered under that exporter's case number will be liquidated at the PRC-wide rate.⁹

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise from the PRC entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) For the exporters listed above, the cash deposit rate will be the rate established in the final results of this review (except, if the rate is zero or *de minimis*, a zero cash deposit rate will be required for that company); (2) for previously investigated or reviewed PRC and non-PRC exporters not listed above that have separate rates, the cash deposit rate will continue to be the existing producer/exporter-specific combination rate published for the most recent period; (3) for all PRC exporters of subject merchandise that have not been found to be eligible for a separate rate, the cash deposit rate will be the PRC-wide rate of 285.63 percent;¹⁰ and (4) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporter(s) that supplied that non-PRC exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping

duties occurred and the subsequent assessment of double antidumping duties.

We are issuing¹¹ and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213 and 19 CFR 351.221(b)(4).

Dated: July 24, 2017.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

1. Summary
2. Background
3. Scope of the Order
4. Non-Market Economy Country Status
5. Separate Rates
6. Surrogate Country
7. Date of Sale
8. Normal Value Comparisons
9. Factor Valuation Methodology
10. Surrogate Values
11. Comparisons to Normal Value
12. Adjustments for Countervailable Subsidies
13. Currency Conversion

[FR Doc. 2017-15942 Filed 7-27-17; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XF557

Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting (webinar).

SUMMARY: The Pacific Fishery Management Council's (Pacific Council) Coastal Pelagic Species Management Team (CPSMT) will hold a meeting via webinar that is open to the public.

DATES: The CPSMT webinar will be held Wednesday, August 16, 2017, from 1 p.m. to 4 p.m. or until business for the day has been completed.

ADDRESSES: The meeting will be held via webinar. A public listening station

is available at the Pacific Council office (see address below). To attend the webinar (1) join the meeting by visiting this link <https://www.gotomeeting.com/webinar/join-webinar>, (<https://www.gotomeeting.com/webinar> <https://global.gotomeeting.com/join/955668125>) (2) enter the Webinar ID: 430-720-091, and (3) enter your name and email address (required). After logging in to the webinar, please (1) dial this TOLL number 1-914-614-3221 (not a toll-free number), (2) enter the attendee phone audio access code 517-298-471, and (3) then enter your audio phone pin (shown after joining the webinar). *Note:* We have disabled Mic/Speakers as an option and require all participants to use a telephone or cell phone to participate. Technical Information and System Requirements: PC-based attendees are required to use Windows® 7, Vista, or XP; Mac®-based attendees are required to use Mac OS® X 10.5 or newer; Mobile attendees are required to use iPhone®, iPad®, Android™ phone or Android tablet (See the GoToMeeting WebinarApps). You may send an email to Mr. Kris Kleinschmidt at Kris.Kleinschmidt@noaa.gov or contact him at (503) 820-2280, extension 411 for technical assistance.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220-1384.

FOR FURTHER INFORMATION CONTACT:

Kerry Griffin, Pacific Council; telephone: (503) 820-2409.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to discuss and consider a draft Terms of Reference for the 2018 review of the National Oceanic and Atmospheric Administration acoustic-trawl survey methodology for Coastal Pelagic Species stocks. The CPSMT will also discuss future meeting planning and public comment may be taken at the discretion of the CPSMT Chair.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for

⁹ See *Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties*, 76 FR 65694 (October 24, 2011).

¹⁰ See *Notice of Final Determination of Sales at Less Than Fair Value: Chlorinated Isocyanurates From the People's Republic of China*, 70 FR 24502, 24505 (May 10, 2005).

¹¹ This notice was originally signed by Ronald K. Lorentzen, Acting Assistant Secretary for Enforcement and Compliance, on June 30, 2017. The notice was not accepted for **Federal Register** publication purposes because of issues with the electronic signature. Therefore, this notice has been signed anew for resubmission to the **Federal Register**.

sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt at (503) 820-2411 at least 10 days prior to the meeting date.

Dated: July 25, 2017.

Tracey L. Thompson,

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

[FR Doc. 2017-15934 Filed 7-27-17; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XF570

Fisheries of the South Atlantic; South Atlantic Fishery Management Council; Public Meetings

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

ACTION: Notice of meetings of the South Atlantic Fishery Management Council's Citizen Science Advisory Panel Action Teams.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold five meetings of its Citizen Science Advisory Panel Action Teams via webinar.

DATES: The meetings will be held Friday, August 11, 2017 at 10 a.m. (Communication/Outreach/Education), Monday, August 14 at 1 p.m. (Projects/Topics Management), Monday, August 14 at 6 p.m. (Volunteers), Tuesday, August 15 at 1 p.m. (Data Management), and Monday, August 28 at 1 p.m. (Finance). Each meeting is scheduled to last approximately 75 minutes. Additional Action Team webinar and plenary webinar dates and times will publish in a subsequent issue in the **Federal Register**.

ADDRESSES:

Meeting address: The meetings will be held via webinar and are open to members of the public. Webinar registration is required and registration links will be posted to the Citizen Science program page of the Council's Web site at www.safmc.net.

Council address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N. Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT:

Amber Von Harten, Citizen Science Program Manager, SAFMC; phone: (843) 302-8433 or toll free: (866) SAFMC-10; fax: (843) 769-4520; email: amber.vonharten@safmc.net.

SUPPLEMENTARY INFORMATION: The South Atlantic Fishery Management Council (Council) created a Citizen Science Advisory Panel Pool in June 2017. The Council appointed members of the Citizen Science Advisory Panel Pool to five Action Teams in the areas of *Volunteers, Data Management, Projects/Topics Management, Finance, and Communication/Outreach/Education* to develop program policies and operations for the Council's Citizen Science Program.

Each Action Team will meet to begin work on developing recommendations on program policies and operations to be reviewed by the Council's Citizen Science Committee.

Items to be addressed during these meetings:

1. Appointment of Action Team Chair(s)
2. Review and Prioritization of Terms of Reference
3. Work Plan for Action Team Tasks
4. Schedule of Action Team Webinar Meetings
5. Other Business

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the council office (see **ADDRESSES**) 3 days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: July 25, 2017.

Tracey L. Thompson,

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

[FR Doc. 2017-15929 Filed 7-27-17; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XF567

South Atlantic Fishery Management Council; Public Meeting

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

ACTION: Notice of public scoping meeting.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold a public scoping meeting via webinar pertaining to Amendment 31 to the Coastal Migratory Pelagics Fishery Management Plan for the Atlantic and

Gulf of Mexico (FMP). The draft amendment includes options to remove Atlantic cobia from the FMP or establish complementary management of Atlantic cobia.

DATES: The public scoping meeting will be held via webinar on August 15, 2017 at 6 p.m. Eastern Standard Time.

ADDRESSES: *Council address:* South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N. Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, SAFMC; phone: (843) 571-4366 or toll free: (866) SAFMC-10; fax: (843) 769-4520; email: kim.iverson@safmc.net.

SUPPLEMENTARY INFORMATION: The Council is soliciting public input on options for the management of Atlantic cobia. Atlantic cobia are currently managed by the Council in federal waters from the Florida/Georgia state line north through New York. Options include continuing efforts to develop a complementary management plan with the Atlantic States Marine Fisheries Commission (ASMFC) or the complete transfer of Atlantic cobia management to the ASMFC. The recreational fishery for Atlantic cobia closed in federal waters earlier this year after NOAA Fisheries determined the annual catch limit would be met. The majority of Atlantic cobia are caught off the coasts of northeastern North Carolina and Virginia are generally harvested from state waters. The Council is considering options for management in order to allow additional flexibility for the fishery.

The public scoping webinar will consist of a presentation by Council staff, a question and answer session, and formal public comment. Written comments will also be accepted via the online comment form. Registration for the webinar is required. Registration information, briefing materials and the public comment form will be available at: <http://safmc.net/safmc-meetings/public-hearing-and-scoping-meeting-schedule/> on or before August 1, 2017. Written comments may also be submitted to the Council office (see **ADDRESSES**). Comments will be accepted until 5 p.m. on Friday, August 18, 2017.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the council office (see **ADDRESSES**) 3 days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: July 25, 2017.

Tracey L. Thompson,

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

[FR Doc. 2017-15926 Filed 7-27-17; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XF569

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 (Council) will hold its 160th meeting.

DATES: The meeting will be held on August 15-16, 2017. The Council will convene on Tuesday, August 15, 2017, from 9 a.m. to 5 p.m., and will reconvene on Wednesday, August 16, 2017, from 9 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at the Courtyard Marriott Isla Verde Beach Resort, 7012 Boca de Cangrejos Avenue, Carolina, Puerto Rico 00979.

FOR FURTHER INFORMATION CONTACT: Caribbean Fishery Management Council, 270 Muñoz Rivera Avenue, Suite 401, San Juan, Puerto Rico 00918; telephone: (787) 766-5926.

SUPPLEMENTARY INFORMATION: The Council will hold its 160th regular Council Meeting to discuss the items contained in the following agenda:

August 15, 2017, 9 a.m.-5 p.m.

- Call to Order
- Election of Officers
- Adoption of Agenda
- Consideration of 159th Council Meeting Verbatim Transcriptions
- Executive Director's Report
- Scientific and Statistical Committee Meeting Report—Richard Appeldoorn
- District Advisory Panel Meeting Recommendations—Graciela Garcia-Moliner
- Dolphin Fish Survey Puerto Rico and the U.S. Virgin Islands Presentation—Mr. Wessley Merten
- Island-based Fishery Management Plans and Draft Environmental Impact Statements
 - Review of Draft Actions and Alternatives for the Draft Environmental Impact Statements

for each Island-Based Fishery Management Plan

- Action 1:* Species to Manage (Final Draft Alternatives Complete)
- Action 2:* Species Groupings (Review Final Draft Alternatives)
- Action 3:* Reference Points (Review Draft Alternatives)
- Action 4:* Essential Fish Habitat for Stocks Not Previously Managed in Federal Waters
- Action 5:* Framework Measures
- Next Steps/Roadmap—Bill Arnold
- Review of Accountability Measure-Based Closures for the 2017 Fishing Year
- Update on Regulatory Amendment 6 to the Reef Fish Fishery Management Plan: Triggering Accountability Measures in the Puerto Rico Exclusive Economic Zone
- Other Business

PUBLIC COMMENT PERIOD—
(5-minute presentations)

August 15, 2017, 5:30 p.m.-6:30 p.m.

- Administrative Matters
 - CY 2017
 - Closed Session

August 16, 2017, 9 a.m.-5 p.m.

- Update on the Commercial Port Sampling Landings Validation Project—Todd Gedamke
 - Outreach and Education Report—Alida Ortiz
 - Octopus Fishery Survey Puerto Rico—Grisel Rodriguez
 - Developing a Fishery Ecosystem Plan—Presentation on Lenfest/PEW Approach to Fishery Ecosystem Plan Development
 - Enforcement Issues:
 - Puerto Rico-DNER
 - U.S. Virgin Islands-DPNR
 - U.S. Coast Guard
 - 1991 DNER/NMFS Memorandum of Understanding
 - NMFS/NOAA
 - Electronic Reporting Project Update—The Nature Conservancy
 - Meetings Attended by Council Members and Staff
 - Other Business
- PUBLIC COMMENT PERIOD—**
(5-minute presentations)

○ Next Meeting
The established times for addressing items on the agenda may be adjusted as necessary to accommodate the timely completion of discussion relevant to the agenda items. To further accommodate discussion and completion of all items on the agenda, the meeting may be extended from, or completed prior to the date established in this notice.

The meeting is open to the public, and will be conducted in English.

Simultaneous interpretation will be available. Fishers and other interested persons are invited to attend and participate with oral or written statements regarding agenda issues.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be subjects for formal action during this meeting. Actions will be restricted to those issues specifically identified 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 that the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. For more information or request for sign language interpretation and/or 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, telephone (787) 766-5926, at least 5 days prior to the meeting date.

Dated: July 25, 2017.

Tracey L. Thompson,

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

[FR Doc. 2017-15927 Filed 7-27-17; 8:45 am]

BILLING CODE 3510-22-P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed addition to and deletions from the Procurement List.

SUMMARY: The Committee is proposing to add a service to the Procurement List that will be furnished by a nonprofit agency employing persons who are blind or have other severe disabilities, and deletes a product and services previously furnished by such agencies.

DATES: *Comments must be received on or before:* August 27, 2017.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia 22202-4149.

FOR FURTHER INFORMATION CONTACT: Amy B. Jensen, Telephone: (703) 603-

7740, Fax: (703) 603-0655, or email
CMTEFedReg@AbilityOne.gov.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51-2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Addition

If the Committee approves the proposed addition, the entities of the Federal Government identified in this notice will be required to provide the service listed below from nonprofit agency employing persons who are blind or have other severe disabilities.

The following service is proposed for addition to the Procurement List for production by the nonprofit agency listed:

Service

Service Type: Base Supply Center Service
Mandatory for: U.S. Army Corps of Engineers, Engineer Research & Development Center, 3909 Halls Ferry Road, Vicksburg, MS
Mandatory Source(s) of Supply: LC Industries, Inc., Durham, NC
Contracting Activity: Dept of the Army, W2R2 USA ENGR R AND D CTR

Deletions

The following product and services are proposed for deletion from the Procurement List:

Product

NSN(s)—Product Name(s): 4610-00-268-9890—Bag, Drinking Water Storage
Mandatory Source(s) of Supply: Huntsville Rehabilitation Foundation, Huntsville, AL
Contracting Activity: Defense Logistics Agency Troop Support

Services

Service Types:
Kitting Service (Assembly)
Belt Weather Kit: (6660-01-024-2638)
Canteen, Water Disposable: (8465-01-062-5854)
Dinnerware Kit: (7360-00-139-0480)
Mop-up Kit, Lateral Line: (4210-01-321-4206)
Assembly of Kit, Hot Food and Drink Service
Mandatory for: GSA, Southwest Supply Center: 819 Taylor Street, Fort Worth, TX
Mandatory Source(s) of Supply: Expanco, Inc., Fort Worth, TX
Contracting Activity: General Services Administration, Fort Worth, TX

Amy B. Jensen,

Director, Business Operations.

[FR Doc. 2017-15964 Filed 7-27-17; 8:45 am]

BILLING CODE 6353-01-P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions and Deletions

AGENCY: Committee For Purchase From People Who Are Blind Or Severely Disabled.

ACTION: Additions to and deletions from the Procurement List.

SUMMARY: This action adds a product and service to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes products and services from the Procurement List previously furnished by such agencies.

DATES: *Date added to the Procurement List:* August 27, 2017.

ADDRESSES: Committee For Purchase From People Who Are Blind Or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia 22202-4149.

FOR FURTHER INFORMATION CONTACT: Amy B. Jensen, Telephone: (703) 603-7740, Fax: (703) 603-0655, or email CMTEFedReg@AbilityOne.gov.

SUPPLEMENTARY INFORMATION:

Additions

On 6/2/2017 (82 FR 25602), the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed addition to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the product and service and impact of the additions on the current or most recent contractors, the Committee has determined that the product and service listed below are suitable for procurement by the Federal Government under 41 U.S.C. 8501-8506 and 41 CFR 51-2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the product and service to the Government.
2. The action will result in authorizing small entities to furnish the product and service to the Government.
3. There are no known regulatory alternatives which would accomplish

the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501-8506) in connection with the product and service proposed for addition to the Procurement List.

End of Certification

Accordingly, the following product and service are added to the Procurement List:

Product

NSN(s)—Product Name(s): MR 13008—Melon Baller
Mandatory Source(s) of Supply: Cincinnati Association for the Blind, Cincinnati, OH
Mandatory for: The requirements of military commissaries and exchanges in accordance with the Code of Federal Regulations, 41 CFR 51-6.4
Contracting Activity: Defense Commissary Agency
Distribution: C-List

Service

Service Type: Custodial Service
Mandatory for: National Park Service, Golden Gate National Recreation Area, Fort Mason, Buildings 101, 201 and 204, San Francisco, CA
Mandatory Source(s) of Supply: Toolworks, Inc., San Francisco, CA
Contracting Activity: National Park Service, San Francisco, CA

Deletions

On 6/2/2017 (82 FR 25602), 6/9/2017 (82 FR 26780), and 6/16/2017 (82 FR 27698), the Committee for Purchase From People Who Are Blind or Severely Disabled published notices of proposed deletions from the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the products and services listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501-8506 and 41 CFR 51-2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.
2. The action may result in authorizing small entities to furnish the products and services to the Government.
3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501-8506) in connection with the products and services deleted from the Procurement List.

End of Certification

Accordingly, the following products and services are deleted from the Procurement List:

Products**NSN(s)—Product Name(s):**

FS1349B—Windbreaker, SCSEP, Forest Service, Dark/Green/Pantone, Various Sizes
 FS509A—Vest, Forest Service, SCSEP, Various Sizes
 FS240—Jeans, Field, Forest Service, Men's, Various Sizes
 FS400—Pants, Field, Forest Service, Men's, Dark Green/Pantone, Wool, Various Sizes
 FS326—Cap, Baseball, Forest Service, Dark Green/Pantone, Nylon Mesh, Various Sizes
 FS521—Cap, SCSEP, Forest Service, Dark Green/Pantone, Nylon Mesh, Various Sizes
 FS9552—Patches, Volunteer, Forest Service, Pkg. of 10
 FS875—Nameplate, Forest Service, Law Enforcement, Gold Plated
 8455-00-NSH-0012—Patches, Volunteer, Forest Service, Pkg. of 10
 8455-00-NSH-0022—Nameplate, Forest Service, Law Enforcement, Gold Plated
 8455-00-NSH-0023—Patch, Forest Service, Law Enforcement, Large
 8455-00-NSH-0024—Patch, Forest Service, Law Enforcement, Small
Mandatory Source(s) of Supply: Human Technologies Corporation, Utica, NY
Contracting Activity: U.S. Forest Service, Washington Office
NSN(s)—Product Name(s): MR 1031—Rag, Cleaning, Red
Mandatory Source(s) of Supply: Winston-Salem Industries for the Blind, Inc., Winston-Salem, NC
Contracting Activity: Defense Commissary Agency
NSN(s)—Product Name(s): 7210-00-682-6504—Mattress, Foam
Mandatory Source(s) of Supply: Lions Volunteer Blind Industries, Inc., Morristown, TN
Contracting Activity: General Services Administration, Fort Worth, TX
NSN(s)—Product Name(s):
 7510-01-431-6520—Foam Stamp Pad, Size #1, 2³/₄" x 4¹/₄", Blue
 7510-01-431-6528—Foam Stamp Pad, Size #3, 4¹/₂" x 7¹/₂", Blue
Mandatory Source(s) of Supply: Cattaraugus County Chapter, NYSARC, Olean, NY
Contracting Activity: General Services Administration, New York, NY

Services

Service Type: Grounds Maintenance Service
Mandatory for:

Eglin Air Force Base: Duke Field, Eglin, FL
 Eglin Air Force Base: East of Memorial Trail (excluding the airfield), Eglin, FL
 Eglin Air Force Base: Navy EOD, Eglin, FL
 Eglin Air Force Base: Ranger Camp, Eglin, FL
 Eglin Air Force Base: Site C-6, Eglin, FL
Mandatory Source(s) of Supply: PRIDE Industries, Roseville, CA

Contracting Activity: DEPT OF THE AIR FORCE, FA2823 AFTC P
Service Type: Administrative Service
Mandatory for: National Aeronautics and Space Administration: Marshall Space Flight Center, 4200 Complex, Marshall Space, AL
Mandatory Source(s) of Supply: The ARC of Madison County, Inc., Huntsville, AL
Contracting Activity: National Aeronautics and Space Administration, NASA Headquarters

Amy B. Jensen,

Director, Business Operations.

[FR Doc. 2017-15965 Filed 7-27-17; 8:45 am]

BILLING CODE 6353-01-P

BUREAU OF CONSUMER FINANCIAL PROTECTION

[Docket No. CFPB-2017-0022]

Agency Information Collection Activities: Comment Request; Correction

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice and request for comment.

SUMMARY: The Bureau of Consumer Financial Protection published a notice in the **Federal Register** of July 19, 2017 concerning a request for comments on the proposed extension without change of an Office of Management and Budget (OMB) control number. The OMB control number in the notice was incorrect.

FOR FURTHER INFORMATION CONTACT: The Consumer Financial Protection Bureau, (Attention: PRA Office), 1700 G Street NW., Washington, DC 20552, (202) 435-9575, or email: CFPB_PRA@cfpb.gov.

Correction

In the **Federal Register** of July 19, 2017 in FR Doc. 2017-15105 on page 33071, in the third column, correct "OMB Control Number" to read: 3170-0042.

Dated: July 24, 2017.

Darrin A. King,

Paperwork Reduction Act Officer, Bureau of Consumer Financial Protection.

[FR Doc. 2017-15981 Filed 7-27-17; 8:45 am]

BILLING CODE 4810-AM-P

DEPARTMENT OF DEFENSE**Department of the Army****Notice of Intent To Grant Exclusive Patent License to Hickies, Inc.; Brooklyn, NY**

AGENCY: Department of the Army, DoD.

ACTION: Notice of intent.

SUMMARY: The Department of the Army hereby gives notice of its intent to grant to Hickies, Inc.; a corporation having its principle place of business at 134 North 4th Street, 2nd Floor, Brooklyn, NY 11249, an exclusive license.

DATES: Written objections must be filed not later than 15 days following publication of this announcement.

ADDRESSES: Send written objections to U.S. Army Research Laboratory Technology Transfer and Outreach Office, RDRL-DPT/Thomas Mulkern, Building 321 Room 110, Aberdeen Proving Ground, MD 21005-5425.

FOR FURTHER INFORMATION CONTACT: Thomas Mulkern, (410) 278-0889, E-Mail: ORTA@arl.army.mil

SUPPLEMENTARY INFORMATION: The Department of the Army plans to grant an exclusive license to Hickies, Inc. in the field of use related to footwear closure systems incorporating rate-actuated tether (RAT) straps relative to the following—

- "Rate-Responsive, Stretchable Devices", US Patent No.: 9,303,717, Filing Date June 26, 2013, Issue Date April 5, 2016.

- "Rate-Responsive, Stretchable Devices (Further Improvements)", US Patent Application No.: 15/057,944, Filing Date March 1, 2016.

The prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the U.S. Army Research Laboratory receives written objections including evidence and argument that establish that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209(e) and 37 CFR 404.7(a)(1)(i). Competing applications completed and received by the U.S. Army Research Laboratory within fifteen (15) days from the date of this published notice will also be treated as objections to the grant of the contemplated exclusive license.

Objections submitted in response to this notice will not be made available to the public for inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 2017-15947 Filed 7-27-17; 8:45 am]

BILLING CODE 5001-03-P

DEPARTMENT OF DEFENSE**Office of the Secretary****[Docket ID: DOD–2017–HA–0036]****Proposed Collection; Comment Request**

AGENCY: Office of the Assistant Secretary of Defense for Health Affairs (OASD HA), DoD.

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995*, the OASD HA is proposing an extension of an existing information collection. Comments are invited on: 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; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 26, 2017.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Mail:* Department of Defense, Office of the Deputy Chief Management Officer, Directorate for Oversight and Compliance, Regulatory and Advisory Committee Division, 4800 Mark Center Drive, Mailbox #24, Suite 08D09B, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public

viewing on the Internet at <http://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

Any associated form(s) for this collection may be located within this same electronic docket and downloaded for review/testing. Follow the instructions at <http://www.regulations.gov> for submitting comments. Please submit comments on any given form identified by docket number, form number, and title.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Decision Support Division, Defense Health Agency, ATTN: Dr. Kimberley Aiyelawo, 7700 Arlington Blvd., Suite 5101, Falls Church, VA 22042–5101, or call 703–681–3636.

SUPPLEMENTARY INFORMATION:

Title: Associated Form; and *OMB Number:* TRICARE Award Fee Provider Survey; OMB Control Number 0720–0048.

Needs and Uses: The information collection requirement is necessary to obtain and record TRICARE network civilian provider-user satisfaction with the administrative processes/services of managed care support contractors (MCSC) in three TRICARE regions within the United States (North, West, and South) and three regions internationally (Europe, Pacific and Latin America). The survey will obtain TRICARE network civilian provider opinions regarding claims processing, customer service, and administrative support by the TRICARE regional contractors. The reports of findings from these surveys, coupled with performance criteria from other sources, will be used by the TRICARE Regional Administrative Contracting Officers to determine incentive award fee determination.

Affected Public: Businesses or other for profit; not for-profit institutions.

Annual Burden Hours: 102.

Number of Respondents: 1,224.

Responses per Respondent: 1.

Annual Responses: 1,224.

Average Burden per Response: 5 minutes per respondent.

Frequency: Monthly.

Respondents are TRICARE network providers which are defined as a person, business, or institution that provides health care.

DHA has delegated oversight of the civilian provider network to the TRICARE Regional Offices. To improve DHA's oversight of the civilian provider network, GAO has recommended OASD HA explore options for improving the civilian provider surveys so that the results of the surveys could be useful to the DHA and to the contractors in identifying civilian provider concerns and developing actions that might mitigate concerns and help ensure the adequacy of the civilian provider network.

The goal of this survey effort is to provide regional Administrative Contracting Officers with information on provider end-user satisfaction with the administrative processes/services of MCSC. Specifically, confidential telephone surveys of civilian network providers will be conducted that focus on three basic business functions provided of claims processing, customer service, and administrative services by the MCSC.

Dated: July 25, 2017.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2017–15980 Filed 7–27–17; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF ENERGY

Orders Granting Authority To Import and Export Natural Gas, To Import and Export Liquefied Natural Gas, Order To Show Cause, Request for Rehearing and Motion for Leave To Answer, Request To Extend Commencement Date, and Vacating Authorization During June 2017

	FE Docket Nos.
Louisiana LNG Energy LLC	14–19–LNG
Golden Pass Products LLC	14–29–LNG
Freeport LNG Expansion, L.P., FLNG Liquefaction, LLC, FLNG Liquefaction 2 LLC, AND FLNG Liquefaction 3 LLC	12–156–LNG
Energia Del Caribe, S.A	10–160–LNG
Lake Charles LNG Export Company, LLC	16–23–NG
Lake Charles Exports, LLC	16–109–LNG
Delfin LNG LLC	16–110–NG
Dominion Cove Point LNG, LP	13–147–LNG
Emera Energy Services, Inc	16–205–LNG
CFE International LLC	17–67–NG
	17–66–NG

	FE Docket Nos.
Chevron U.S.A. Inc	17-71-NG
Trailstone NA Logistics, LLC	17-50-NG
Freeport LNG Development, L.P	17-23-LNG

AGENCY: Office of Fossil Energy,
Department of Energy.

ACTION: Notice of orders.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy gives notice that during June 2017, it issued orders granting authority to import and export natural gas, to import and export liquefied natural gas (LNG), Order to Show Cause, Request for Rehearing and Motion for Leave to Answer, Request to Extend Commencement Date, and

vacating authority. These orders are summarized in the attached appendix and may be found on the FE Web site at <http://energy.gov/fe/listing-doe-fe-authorizations-orders-issued-2017>.

They are also available for inspection and copying in the U.S. Department of Energy (FE-34), Division of Natural Gas Regulation, Office of Regulation and International Engagement, Office of Fossil Energy, Docket Room 3E-033, Forrestal Building, 1000 Independence

Avenue SW., Washington, DC 20585, (202) 586-9478. The Docket Room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, on July 24, 2017.

John A. Anderson,

Director, Office of Regulation and International Engagement, Office of Oil and Natural Gas.

Appendix

DOE/FE ORDERS GRANTING IMPORT/EXPORT AUTHORIZATIONS

No order number assigned	06/12/17	14-19-LNG; 14-29-LNG	Louisiana LNG Energy LLC.	Order to Show Cause.
No Order Number Assigned.	06/23/17	12-156-LNG	Golden Pass Products LLC.	Order granting Request for Rehearing and Motion for Leave to Answer for the Purpose of Further Consideration.
2913-B	06/07/17	10-160-LNG	Freeport LNG Expansion, L.P., FLNG Liquefaction, LLC, FLNG Liquefaction 2, LLC, and FLNG Liquefaction.	Order 2913-B granting blanket authority to Request to Extend Commencement Date of export authorization.
3795-A	06/16/17	16-23-NG	Energia del Caribe, S.A. ..	Order 3795-A vacating blanket authority to export natural gas to Mexico.
4010	06/29/17	16-109-LNG	Lake Charles LNG Export Company, LLC.	Opinion and Order 4010 granting long-term, multi-contract authority to export LNG by vessel from the Lake Charles Terminal in Lake Charles, Louisiana, to Free Trade and Non-free Trade Agreement Nations.
4011	06/29/17	16-110-LNG	Lake Charles Exports, LLC.	Opinion and Order 4011 granting long-term multi-contract authority to export LNG by vessel from the Lake Charles Terminal in Lake Charles, Louisiana, to Free Trade and Non-free Trade Agreement Nations.
4028	06/01/17	13-147-LNG	Delfin LNG LLC	Order 4028 granting long-term, multi-contract authority to export LNG by vessel from the Proposed Floating Delfin Liquefaction Facility, offshore of Cameron Parish, Louisiana, to Non-free Trade Agreement Nations.
4046	06/02/17	16-205-LNG	Dominion Cove Point LNG, LP.	Order 4046 granting blanket authority to export LNG by vessel from the Cove Point Terminal located in Calvert County, Maryland, to Free Trade and Non-free Trade Agreement Nations.
4050	06/08/17	17-67-NG	Emera Energy Services, Inc.	Order 4050 granting blanket authority to import/export natural gas from/to Canada.
4051	06/08/17	17-66-NG	CFE International LLC	Order 4051 granting blanket authority to import/export natural gas from/to Mexico, and vacating prior authorization.
4052	06/08/17	17-71-NG	Chevron U.S.A. Inc.	Order 4052 granting blanket authority to import/export natural gas from/to Canada.
4053	06/26/17	17-50-NG	TrailStone NA Logistics, LLC.	Order 4053 granting blanket authority to import/export natural gas from/to Canada/Mexico, to import LNG from Canada/Mexico by truck, to export LNG to Canada/Mexico by vessel, to import LNG from various international sources by vessel, and vacating prior authorization.
4054	06/26/17	17-23-LNG	Freeport LNG Development, L.P.	Order 4054 granting blanket authority to export previously imported LNG by vessel.

[FR Doc. 2017-15932 Filed 7-27-17; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission****Combined Notice of Filings #1**

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER16-1923-000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.19a(b): Refund Report (ER16-1923-000 and -002) to be effective N/A.
Filed Date: 7/21/17.
Accession Number: 20170721-5120.
Comments Due: 5 p.m. ET 8/11/17.
Docket Numbers: ER17-2029-001.
Applicants: Entergy Arkansas, Inc.
Description: Tariff Amendment: EAI-ESI Reimbursement Agreement Extension to be effective 12/31/9998.
Filed Date: 7/20/17.
Accession Number: 20170720-5136.
Comments Due: 5 p.m. ET 8/10/17.
Docket Numbers: ER17-2030-001.
Applicants: Entergy Louisiana, LLC.
Description: Tariff Amendment: ELL-ESI Reimbursement Agreement Extension to be effective 12/31/9998.
Filed Date: 7/20/17.
Accession Number: 20170720-5138.
Comments Due: 5 p.m. ET 8/10/17.
Docket Numbers: ER17-2031-001.
Applicants: Entergy Mississippi, Inc.
Description: Tariff Amendment: EMI-ESI Reimbursement Agreement Extension to be effective 12/31/9998.
Filed Date: 7/20/17.
Accession Number: 20170720-5139.
Comments Due: 5 p.m. ET 8/10/17.
Docket Numbers: ER17-2033-001.
Applicants: Entergy New Orleans, Inc.
Description: Tariff Amendment: ENO-ESI Reimbursement Agreement to be effective 12/31/9998.
Filed Date: 7/20/17.
Accession Number: 20170720-5140.
Comments Due: 5 p.m. ET 8/10/17.
Docket Numbers: ER17-2034-001.
Applicants: Entergy Texas, Inc.
Description: Tariff Amendment: ETI-ESI Reimbursement Agreement to be effective 12/31/9998.
Filed Date: 7/20/17.
Accession Number: 20170720-5141.
Comments Due: 5 p.m. ET 8/10/17.
Docket Numbers: ER17-2115-000.
Applicants: Northern States Power Company, a Minnesota corporation.

Description: § 205(d) Rate Filing: NSPM Concurrence to OTP RS 110, Suppl No. 3 to be effective 4/16/2016.

Filed Date: 7/21/17.

Accession Number: 20170721-5001.

Comments Due: 5 p.m. ET 8/11/17.

Docket Numbers: ER17-2116-000.

Applicants: Midcontinent

Independent System Operator Inc., ITC Midwest LLC.

Description: § 205(d) Rate Filing: 2017-07-21 Revisions to ITCM Attachment O for Abandoned Plant Incentive to be effective 9/20/2017.

Filed Date: 7/21/17.

Accession Number: 20170721-5040.

Comments Due: 5 p.m. ET 8/11/17.

Docket Numbers: ER17-2118-000.

Applicants: ISO New England Inc., New England Power Pool Participants Comm.

Description: § 205(d) Rate Filing: Rev. to Sec. II.44(1)(a) to Conform with Day-Ahead Energy Mkt. Sched. Timeline to be effective 9/20/2017.

Filed Date: 7/21/17.

Accession Number: 20170721-5092.

Comments Due: 5 p.m. ET 8/11/17.

Docket Numbers: ER17-2119-000.

Applicants: Energy Consulting Services, LLC.

Description: Notice of cancellation of Market-Based Rate Tariff of Energy Consulting Services, LLC.

Filed Date: 7/19/17.

Accession Number: 20170720-0015.

Comments Due: 5 p.m. ET 8/9/17.

Take notice that the Commission received the following foreign utility company status filings:

Docket Numbers: FC17-4-000.

Applicants: I Squared Capital.

Description: Self-Certification of FUCO on behalf of Orazul Companies.

Filed Date: 7/21/17.

Accession Number: 20170721-5066.

Comments Due: 5 p.m. ET 8/11/17.

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: July 21, 2017.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017-15912 Filed 7-27-17; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission**

[Docket Nos. CP15-554-000, CP15-554-001, CP15-555-000, CP15-556-000]

Atlantic Coast Pipeline, LLC, Dominion Energy Transmission, Inc., Piedmont Natural Gas Company, Inc.; Notice of Availability of the Final Environmental Impact Statement for the Proposed Atlantic Coast Pipeline and Supply Header Project

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared a final environmental impact statement (EIS) for the Atlantic Coast Pipeline (ACP) and Supply Header Project (SHP) as proposed by Atlantic Coast Pipeline, LLC (Atlantic) and Dominion Energy Transmission, Inc. (DETI), respectively, in the above-referenced dockets. Atlantic and DETI request authorization to construct and operate a total of 642.0 miles of natural gas transmission pipeline and associated facilities, and three new natural gas-fired compressor stations; and to modify four existing compressor stations. The projects would provide about 1.44 billion cubic feet per day of natural gas to electric generation, distribution, and end use markets in Virginia and North Carolina. In addition, Atlantic and Piedmont Natural Gas Co., Inc. (Piedmont) request authorization to allow Atlantic to lease capacity on Piedmont's existing pipeline distribution system in North Carolina for use by Atlantic (Capacity Lease Proposal). No construction or facility modifications are proposed with the Capacity Lease.

The final EIS assesses the potential environmental effects of the construction and operation of the projects in accordance with the requirements of the National Environmental Policy Act (NEPA). The FERC staff concludes that approval of the projects would have some adverse and significant environmental impacts; however, the majority of impacts would be reduced to less-than-significant levels with the implementation of the Atlantic's and DETI's proposed

mitigation and the additional measures recommended in the EIS.

The U.S. Department of Agriculture—Forest Service (FS); U.S. Army Corps of Engineers; U.S. Environmental Protection Agency; U.S. Fish and Wildlife Service; West Virginia Department of Environmental Protection; and West Virginia Division of Natural Resources participated as cooperating agencies in the preparation of the final EIS. Cooperating agencies have jurisdiction by law or special expertise with respect to resources potentially affected by the proposals and participate in the NEPA analysis. Further, the FS may use the EIS when it considers amendments to Land and Resource Management Plans (LRMPs) and authorizations for special use permits (SUPs) for the proposed crossings of the Monongahela National Forest (MNF) and George Washington National Forest (GWNF). Although the cooperating agencies provide input to the conclusions and recommendations presented in the final EIS, each agency may present its own conclusions and recommendations in its respective record of decision or determination for the projects.

The final EIS addresses the potential environmental effects of the construction and operation of the following project facilities:

ACP would include:

- 519.7 miles of new 42- and 36-inch-diameter natural gas pipeline in West Virginia, Virginia, and North Carolina;
- 84.8 miles of 20- and 16-inch-diameter natural gas pipeline in Virginia and North Carolina;
- three new compressor stations in Lewis County, West Virginia; Buckingham County, Virginia; and Northampton County, North Carolina; and
- nine meter stations, along with pig launchers/receivers and mainline valves.

SHP would include:

- 37.5 miles of new 30-inch-diameter natural gas pipeline in Pennsylvania and West Virginia;
- modifications at four existing compressor stations in Westmoreland and Green Counties, Pennsylvania and Marshall and Wetzel Counties, West Virginia;
- abandonment of existing compressor units and associated facilities in Wetzel County, West Virginia; and

- one meter station, along with pig launchers/receivers and mainline valves.

Actions of the Forest Service

The FS's purpose and need for the proposed action is to respond to a special use application submitted by Atlantic on November 12, 2015, to allow the construction and operation of ACP on National Forest System (NFS) lands managed by the MNF and GWNF. If the FS decides to authorize the pipeline crossing of NFS lands and issue SUPs, the FS has determined that amendments to each national forest LRMP would be needed.

Pursuant to Title 40 Code of Federal Regulations Part 1506.3(c) (40 CFR 1506.3(c)), the FS may adopt and use this EIS developed by FERC to consider authorization for the construction and operation of the ACP crossing NFS lands. Further, the FS may use this EIS when it considers amendments to the LRMPs that would be required for the proposed crossings of the MNF and GWNF.

Forest Service's Draft Record of Decision

After issuance of the final EIS, the FS will release a single draft Record of Decision (ROD) for the authorization of a SUP to Atlantic for use of and to occupy NFS lands to construct, operate, maintain, and eventually decommission a natural gas pipeline that crosses lands administered by the MNF and GWNF; and for approval of the project-specific LRMP amendments associated with implementing the ACP on the MNF and the GWNF. The Regional Foresters (RFs) in the Eastern Region (for the MNF) and the Southern Region (for the GWNF) will be the responsible officials for the ROD. The RF for the Eastern Region has determined that two parts of the MNF LRMP, where four standards would be modified by a Forest Plan amendment (section 4.8 of the final EIS), meet the substantive requirements of the FS planning regulations (36 CFR 219) and could be implemented without impairing the long-term productivity of NFS lands. Similarly, the RF for the Southern Region has determined that six parts of the GWNF LRMP, where nine standards would be modified by a Forest Plan amendment, meet the substantive requirements of the FS planning regulations and could be implemented without impairing the long-term productivity on NFS lands. With the amended LRMPs, the ACP would be consistent with both Forests' LRMPs. This draft ROD will be based on a review of the environmental analysis disclosed in the final EIS; the project

record; Atlantic's proposed Construction, Operation, and Maintenance Plan; comments received from the public, partners, and other agencies; and consideration of the 36 CFR 219 requirements for amending a Forest Plan.

The draft ROD is subject to the FS pre-decision objection process pursuant to the provisions available at 36 CFR part 218, subparts A and B (published in the **Federal Register** Vol. 78, No. 59 at 18481 [March 27, 2013]). Objections to the FS draft ROD on the authorization of the pipeline and the LRMP amendments must be filed within 45 calendar days from the publication date of the legal notice of the opportunity to object in *The Milwaukee Journal/Sentinel* and *Atlanta Journal-Constitution*, which are the newspapers of RODs made by the Eastern Region and Southern Region RFs. Notices will also be published in the *Inter-Mountain* and *The Roanoke Times* for local notification of the FS draft ROD. The legal notices will contain the details of the objection process. The FS must respond to all objections received before it makes a final decision.

A copy of the FS draft ROD and the legal notices for objections can be obtained by any of the following methods:

For the GWNF:

- *Internet Web site:* <http://www.fs.usda.gov/gwj>;
- *Email:* kovercash@fs.fed.us; or
- *Regular mail:* Karen Overcash, George Washington and Jefferson National Forests, 5162 Valleypointe Parkway, Roanoke, VA 24019; telephone: (540) 265-5100.

For the MNF:

- *Internet Web site:* <http://www.fs.usda.gov/mnf>;
- *Email:* karenlstevens@fs.fed.us; or
- *Regular mail:* Karen Stevens, Monongahela National Forest, 200 Sycamore Street, Elkins, WV 26241; telephone (304) 636-1800.

Distribution of the Final Environmental Impact Statement

The FERC staff mailed copies of the final EIS to federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American tribes; potentially affected landowners and other interested individuals and groups; newspapers and libraries in the project area; and parties to this proceeding. Paper copy versions of this final EIS were mailed to those specifically requesting them; all others received a CD version. In addition, the final EIS is available for public viewing on the

¹ A pipeline pig is a device used to clean or inspect a pipeline. A pig launcher/receiver is an aboveground facility where pigs are inserted or retrieved from the pipeline.

FERC's Web site (www.ferc.gov) using the eLibrary link. A limited number of copies of the final EIS are available for distribution and public inspection at: Federal Energy Regulatory Commission, Public Reference Room, 888 First Street NE., Room 2A, Washington, DC 20426 (202) 502-8371.

Additional information about the projects is available from the Commission's Office of External Affairs, at (866) 208-FERC, or on the FERC Web site (www.ferc.gov) using the eLibrary link. Click on the eLibrary link, click on General Search, and enter the docket number excluding the last three digits in the Docket Number field (*i.e.*, CP15-554, CP15-555, or CP15-556). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov or toll free at (866) 208-3676; for TTY, contact (202) 502-8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription that allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to www.ferc.gov/docs-filing/esubscription.asp to subscribe.

Dated: July 21, 2017.

Kimberly D. Bose,
Secretary.

[FR Doc. 2017-15911 Filed 7-27-17; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP17-473-000]

National Fuel Gas Supply Corporation; Notice of Request Under Blanket Authorization

Take notice that on July 14, 2017, National Fuel Gas Supply Corporation (National Fuel), 6363 Main Street, Williamsville, New York 14221, filed a prior notice application pursuant to sections 157.205 and 157.216 of the Federal Energy Regulatory Commission's (Commission) regulations under the Natural Gas Act (NGA), and National Fuel's blanket certificate issued in Docket No. CP83-4-000. National Fuel requests authorization to

abandon one injection/withdrawal (I/W) storage well in its Henderson Storage Field (Henderson), and remove a portion of the associated well line, all located in Irwin Township, Venango County, Pennsylvania, all as more fully set forth in the request, which is on file with the Commission and open to public inspection. The filing may also be viewed on the Web at <http://www.ferc.gov> using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at FERCOnlineSupport@ferc.gov or call toll-free, (866) 208-3676 or TTY, (202) 502-8659.

Specifically National Fuel proposes to abandon Well 3168 in Henderson and removal of approximately 30 feet of 4-inch-diameter well line NW-3168 that connects Well 3168 to branch line N14SB1, which is connected to N36S, an 8-inch storage line looping around the field, all located in Irwin Township, Venango County, Pennsylvania.

Any questions regarding this application should be directed to Alice A. Curtiss Deputy General Counsel, National Fuel Gas Supply Corporation, 6363 Main Street, Williamsville, New York 14221-5887 or phone (716) 857-7075, or by email at curtissa@natfuel.com.

Any person or the Commission's staff may, within 60 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the regulations under the NGA (18 CFR 157.205), a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the allowed time for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the NGA.

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding, or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS)

or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenter will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the eFiling link at <http://www.ferc.gov>. Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

Dated: July 24, 2017.

Kimberly D. Bose,
Secretary.

[FR Doc. 2017-15915 Filed 7-27-17; 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: EC17-140-000.

Applicants: Wildorado Wind, LLC.

Description: Application for Approval Under Section 203 of the Federal Power Act of Wildorado Wind, LLC.

Filed Date: 7/21/17.

Accession Number: 20170721-5189.

Comments Due: 5 p.m. ET 8/11/17.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG17–130–000.
Applicants: Stuttgart Solar, LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Stuttgart Solar, LLC.
Filed Date: 7/21/17.

Accession Number: 20170721–5196.
Comments Due: 5 p.m. ET 8/11/17.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER17–2120–000.
Applicants: California Independent System Operator Corporation.
Description: § 205(d) Rate Filing: 2017–07–21 DWP EIM Implementation Agreement to be effective 10/1/2017.
Filed Date: 7/21/17.

Accession Number: 20170721–5164.
Comments Due: 5 p.m. ET 8/11/17.

Docket Numbers: ER17–2121–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2017–07–24 Termination of E&Ps and FCA Project No. J392 to be effective 7/25/2017.

Filed Date: 7/24/17.
Accession Number: 20170724–5069.
Comments Due: 5 p.m. ET 8/14/17.
Docket Numbers: ER17–2122–000.
Applicants: Arkwright Summit Wind Farm LLC.

Description: § 205(d) Rate Filing: Revised Tariff re MBR Docket No. to be effective 7/25/2017.

Filed Date: 7/24/17.
Accession Number: 20170724–5085.
Comments Due: 5 p.m. ET 8/14/17.
Docket Numbers: ER17–2123–000.
Applicants: Blackstone Wind Farm, LLC.

Description: § 205(d) Rate Filing: Revised MBR Tariff re Order No. 819 to be effective 7/25/2017.

Filed Date: 7/24/17.
Accession Number: 20170724–5086.
Comments Due: 5 p.m. ET 8/14/17.
Docket Numbers: ER17–2124–000.
Applicants: Blackstone Wind Farm II LLC.

Description: § 205(d) Rate Filing: Second Revised Tariff re Order No. 819 to be effective 7/25/2017.

Filed Date: 7/24/17.
Accession Number: 20170724–5087.
Comments Due: 5 p.m. ET 8/14/17.
Docket Numbers: ER17–2125–000.
Applicants: Headwaters Wind Farm LLC.

Description: § 205(d) Rate Filing: First Revised Tariff to be effective 7/25/2017.
Filed Date: 7/24/17.
Accession Number: 20170724–5088.

Comments Due: 5 p.m. ET 8/14/17.
Docket Numbers: ER17–2126–000.
Applicants: High Trail Wind Farm, LLC.

Description: § 205(d) Rate Filing: Revised MBR Tariff re 819 AS to be effective 7/25/2017.

Filed Date: 7/24/17.
Accession Number: 20170724–5089.
Comments Due: 5 p.m. ET 8/14/17.
Docket Numbers: ER17–2127–000.
Applicants: Marble River, LLC.
Description: § 205(d) Rate Filing: Revised Tariff re 819 AS to be effective 7/25/2017.

Filed Date: 7/24/17.
Accession Number: 20170724–5090.
Comments Due: 5 p.m. ET 8/14/17.
Docket Numbers: ER17–2128–000.
Applicants: Meadow Lake Wind Farm LLC.

Description: § 205(d) Rate Filing: Revised Tariff re 819 AS to be effective 7/25/2017.

Filed Date: 7/24/17.
Accession Number: 20170724–5091.
Comments Due: 5 p.m. ET 8/14/17.
Docket Numbers: ER17–2129–000.
Applicants: Meadow Lake Wind Farm II LLC.

Description: § 205(d) Rate Filing: Tariff Revisions re 819 AS to be effective 7/25/2017.

Filed Date: 7/24/17.
Accession Number: 20170724–5095.
Comments Due: 5 p.m. ET 8/14/17.
Docket Numbers: ER17–2130–000.
Applicants: Meadow Lake Wind Farm III LLC.

Description: § 205(d) Rate Filing: Revised Tariff re 819 AS to be effective 7/25/2017.

Filed Date: 7/24/17.
Accession Number: 20170724–5096.
Comments Due: 5 p.m. ET 8/14/17.
Docket Numbers: ER17–2131–000.
Applicants: Meadow Lake Wind Farm IV LLC.

Description: § 205(d) Rate Filing: Revised Tariff re 819 AS to be effective 7/25/2017.

Filed Date: 7/24/17.
Accession Number: 20170724–5097.
Comments Due: 5 p.m. ET 8/14/17.
Docket Numbers: ER17–2132–000.
Applicants: Meadow Lake Wind Farm V LLC.

Description: § 205(d) Rate Filing: Revised Tariff re Docket No to be effective 7/25/2017.

Filed Date: 7/24/17.
Accession Number: 20170724–5098.
Comments Due: 5 p.m. ET 8/14/17.
Docket Numbers: ER17–2133–000.
Applicants: Old Trail Wind Farm, LLC.

Description: § 205(d) Rate Filing: Revised Tariff re 819 AS to be effective 7/25/2017.

Filed Date: 7/24/17.
Accession Number: 20170724–5099.
Comments Due: 5 p.m. ET 8/14/17.
Docket Numbers: ER17–2134–000.
Applicants: Duke Energy Carolinas, LLC.

Description: Tariff Cancellation: Cancellation of TSA Filing to be effective 7/25/2017.

Filed Date: 7/24/17.
Accession Number: 20170724–5100.
Comments Due: 5 p.m. ET 8/14/17.
Docket Numbers: ER17–2135–000.
Applicants: Paulding Wind Farm II LLC.

Description: § 205(d) Rate Filing: Revised Tariff re 819 AS to be effective 7/25/2017.

Filed Date: 7/24/17.
Accession Number: 20170724–5104.
Comments Due: 5 p.m. ET 8/14/17.
Docket Numbers: ER17–2136–000.
Applicants: Paulding Wind Farm III LLC.

Description: § 205(d) Rate Filing: Revised MBR Tariff re Docket to be effective 7/25/2017.

Filed Date: 7/24/17.
Accession Number: 20170724–5105.
Comments Due: 5 p.m. ET 8/14/17.
Docket Numbers: ER17–2137–000.
Applicants: Sustaining Power Solutions LLC.

Description: § 205(d) Rate Filing: Revised Tariff re 819 AS to be effective 7/25/2017.

Filed Date: 7/24/17.
Accession Number: 20170724–5106.
Comments Due: 5 p.m. ET 8/14/17.
Docket Numbers: ER17–2138–000.
Applicants: Chief Conemaugh Power, LLC.

Description: § 205(d) Rate Filing: Revised MBR Tariff to be effective 7/25/2017.

Filed Date: 7/24/17.
Accession Number: 20170724–5131.
Comments Due: 5 p.m. ET 8/14/17.
Docket Numbers: ER17–2139–000.
Applicants: Chief Keystone Power, LLC.

Description: § 205(d) Rate Filing: Revised MBR Tariff to be effective 7/25/2017.

Filed Date: 7/24/17.
Accession Number: 20170724–5134.
Comments Due: 5 p.m. ET 8/14/17.

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: July 24, 2017.

Kimberly D. Bose,
Secretary.

[FR Doc. 2017-15913 Filed 7-27-17; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. EL17-81-000; QF83-118-002]

Covanta Marion, Inc.; Notice of Petition for Enforcement

Take notice that on July 21, 2017, Covanta Marion, Inc., filed a Petition for Enforcement, pursuant to section 210(h)(2)(B) of the Public Utility Regulatory Policies Act of 1978 (PURPA), requesting the Federal Energy Regulatory Commission (Commission) to exercise its authority and initiate enforcement action against the Public Utility Commission of Oregon (OPUC) to remedy OPUC's alleged improper implementation of PURPA.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the eFiling link at <http://www.ferc.gov>. Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at <http://www.ferc.gov>, using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email FERCOnlineSupport@ferc.gov, or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Comment Date: 5:00 p.m. Eastern Time on August 11, 2017.

Dated: July 24, 2017.

Kimberly D. Bose,
Secretary.

[FR Doc. 2017-15917 Filed 7-27-17; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL17-80-000]

The City of Alexandria, Louisiana; Notice of Filing.

Take notice that on July 20, 2017, pursuant to section 207(a)(5) of the Commission's Rules of Practice and Procedure¹, the City of Alexandria, Louisiana filed a petition for approval of a revenue requirement for reactive power and voltage control from generation sources service, all as more fully explained in the petition.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the eFiling link at <http://www.ferc.gov>. Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the

¹ 18 CFR 385.207(a)(5) (2014).

Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at <http://www.ferc.gov>, using the eLibrary link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email FERCOnlineSupport@ferc.gov, or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Comment Date: 5:00 p.m. Eastern Time on August 10, 2017.

Dated: July 21, 2017.

Kimberly D. Bose,
Secretary.

[FR Doc. 2017-15916 Filed 7-27-17; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP17-468-000]

Texas Eastern Transmission, LP; Notice of Intent To Prepare an Environmental Assessment for the Proposed Marshall County Mine Panel 18W Project and Request for Comments on Environmental Issues

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) that will discuss the environmental impacts of the Marshall County Mine Panel 18W Project involving construction and operation of facilities by Texas Eastern Transmission, LP (Texas Eastern) in Marshall County, West Virginia. The Commission will use this EA in its decision-making process to determine whether the project is in the public convenience and necessity.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies on the project. You can make a difference by providing us with your specific comments or concerns about the project. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. Your input will help the Commission staff determine what issues they need to evaluate in the EA. To ensure that your comments are timely and properly recorded, please send your comments so

that the Commission receives them in Washington, DC on or before August 23, 2017.

If you sent comments on this project to the Commission before the opening of this docket on June 30, 2017, you will need to file those comments in Docket No. CP17-468-000 to ensure they are considered as part of this proceeding.

This notice is being sent to the Commission's current environmental mailing list for this project. State and local government representatives should notify their constituents of this proposed project and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, a pipeline company representative may contact you about the acquisition of an easement to construct, operate, and maintain the proposed facilities. The company would seek to negotiate a mutually acceptable agreement. However, if the Commission approves the project, that approval conveys with it the right of eminent domain. Therefore, if easement negotiations fail to produce an agreement, the pipeline company could initiate condemnation proceedings where compensation would be determined in accordance with state law.

Texas Eastern provided landowners with a fact sheet prepared by the FERC entitled "An Interstate Natural Gas Facility On My Land? What Do I Need To Know?" This fact sheet addresses a number of typically asked questions, including the use of eminent domain and how to participate in the Commission's proceedings. It is also available for viewing on the FERC Web site (www.ferc.gov).

Public Participation

For your convenience, there are three methods you can use to submit your comments to the Commission. The Commission encourages electronic filing of comments and has expert staff available to assist you at (202) 502-8258 or FercOnlineSupport@ferc.gov. Please carefully follow these instructions so that your comments are properly recorded.

(1) You can file your comments electronically using the *eComment* feature on the Commission's Web site (www.ferc.gov) under the link to *Documents and Filings*. This is an easy method for submitting brief, text-only comments on a project;

(2) You can file your comments electronically by using the *eFiling* feature on the Commission's Web site (www.ferc.gov) under the link to *Documents and Filings*. With eFiling, you can provide comments in a variety

of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on "eRegister." If you are filing a comment on a particular project, please select "Comment on a Filing" as the filing type; or

(3) You can file a paper copy of your comments by mailing them to the following address. Be sure to reference the project docket number (CP17-468-000) with your submission: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Room 1A, Washington, DC 20426.

Summary of the Proposed Project

Texas Eastern proposes to excavate and elevate 1.6-mile-sections of each of its Lines 10 (30-inch-diameter), 15 (30-inch-diameter), 30 (36-inch-diameter), and a 1.5-mile-long section of its Line 25 (36-inch-diameter) to minimize and monitor potential strains on the pipelines due to anticipated longwall mining activities of Marshall Coal. Concurrent with pipeline elevation, portions of two of the lines, Lines 10 and 15, would be replaced with new pipe to accommodate a minimum Class 2 design.¹ Texas Eastern will also perform maintenance activities on sections of Lines 25 and 30. The four mainline sections will be returned to natural gas service while remaining elevated using sandbags and skids during the longwall mining activities and potential ground subsidence. Once the mining-induced subsidence and the 2017-2018 heating season have both ended, the two sections of pipeline located within wetlands will be removed and the four elevated pipeline sections will be re-installed belowground, hydrostatically tested, and placed back into service.

The general location of the project facilities is shown in appendix 1.²

Land Requirements for Construction

Construction workspace would disturb about 56.9 acres of land for the pipeline excavation, elevation, and/or

¹ Lines 10 and 15 were installed prior to the effective date of the Natural Gas Pipeline Safety Act, and are grandfathered to operate at greater than 72% of Specified Minimum Yield Strength (SMYS). The portions of these pipelines included in this Project will be replaced with pipe that meets or exceeds the current Pipeline and Hazardous Materials Safety Administration regulations. See 49 CFR 192.611(a).

² The appendices referenced in this notice will not appear in the **Federal Register**. Copies of appendices were sent to all those receiving this notice in the mail and are available at www.ferc.gov using the link called "eLibrary" or from the Commission's Public Reference Room, 888 First Street NE., Washington, DC 20426, or call (202) 502-8371. For instructions on connecting to eLibrary, refer to the last page of this notice.

replacement. Following construction, Texas Eastern would maintain about 38.2 acres of existing right-of-way for permanent operation of the project's facilities; the remaining acreage would be restored and revert to former uses.

The EA Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires us³ to discover and address concerns the public may have about proposals. This process is referred to as scoping. The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this notice, the Commission requests public comments on the scope of the issues to address in the EA. We will consider all filed comments during the preparation of the EA.

In the EA we will discuss impacts that could occur as a result of the construction and operation of the proposed project under these general headings:

- Geology and soils;
- land use;
- water resources, fisheries, and wetlands;
- cultural resources;
- vegetation and wildlife;
- air quality and noise;
- endangered and threatened species;
- public safety; and
- cumulative impacts

We will also evaluate reasonable alternatives to the proposed project or portions of the project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

The EA will present our independent analysis of the issues. The EA will be available in the public record through eLibrary. Depending on the comments received during the scoping process, we may also publish and distribute the EA to the public for an allotted comment period. We will consider all comments on the EA before making our recommendations to the Commission. To ensure we have the opportunity to consider and address your comments, please carefully follow the instructions in the Public Participation section, beginning on page 2.

With this notice, we are asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues of this project to

³ We, us, and our refer to the environmental staff of the Commission's Office of Energy Projects.

formally cooperate with us in the preparation of the EA.⁴ Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the Public Participation section of this notice.

Consultations Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations for section 106 of the National Historic Preservation Act, we are using this notice to initiate consultation with the applicable State Historic Preservation Office (SHPO), and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the project's potential effects on historic properties.⁵ We will define the project-specific Area of Potential Effects (APE) in consultation with the SHPO as the project develops. On natural gas facility projects, the APE at a minimum encompasses all areas subject to ground disturbance (examples include construction right-of-way, contractor/pipe storage yards, compressor stations, and access roads). Our EA for this project will document our findings on the impacts on historic properties and summarize the status of consultations under section 106.

Environmental Mailing List

The environmental mailing list includes federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American Tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the project. We will update the environmental mailing list as the analysis proceeds to ensure that we send the information related to this environmental review to all individuals, organizations, and government entities

interested in and/or potentially affected by the proposed project.

If we publish and distribute the EA, copies of the EA will be sent to the environmental mailing list for public review and comment. If you would prefer to receive a paper copy of the document instead of the CD version or would like to remove your name from the mailing list, please return the attached Information Request (appendix 2).

Becoming an Intervenor

In addition to involvement in the EA scoping process, you may want to become an intervenor which is an official party to the Commission's proceeding. Intervenor play a more formal role in the process and are able to file briefs, appear at hearings, and be heard by the courts if they choose to appeal the Commission's final ruling. An intervenor formally participates in the proceeding by filing a request to intervene. Instructions for becoming an intervenor are in the Document-less Intervention Guide under the e-filing link on the Commission's Web site. Motions to intervene are more fully described at <http://www.ferc.gov/resources/guides/how-to/intervene.asp>.

Additional Information

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208-FERC, or on the FERC Web site at www.ferc.gov using the eLibrary link. Click on the eLibrary link, click on General Search and enter the docket number, excluding the last three digits in the Docket Number field (*i.e.*, CP17-468). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at FercOnlineSupport@ferc.gov or toll free at (866) 208-3676, or for TTY, contact (202) 502-8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to www.ferc.gov/docs-filing/esubscription.asp.

Finally, public sessions or site visits will be posted on the Commission's calendar located at www.ferc.gov/EventCalendar/EventsList.aspx along with other related information.

Dated: July 24, 2017.

Kimberly D. Bose,
Secretary.

[FR Doc. 2017-15914 Filed 7-27-17; 8:45 am]

BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OW-2017-0260; FRL-9965-39-OW]

Request for Scientific Views: Draft Updated Aquatic Life Ambient Water Quality Criteria for Aluminum in Freshwater

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Availability.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of Draft Updated Aquatic Life Ambient Water Quality Criteria for Aluminum in Freshwater for public comment. EPA first released freshwater criteria for aluminum in 1988 to protect aquatic life from harmful effects of aluminum toxicity. EPA is updating its recommended aluminum criteria to reflect the latest science and to provide users the flexibility to develop site-specific criteria based on site-specific water chemistry. The draft document provides a scientific assessment of ecological effects and is not a regulation. Following closure of this 60-day public comment period, EPA will consider the comments, revise the draft document, as appropriate, and then publish a final document that will provide recommendations for states and authorized tribes to establish water quality standards. The recommendations found in this draft document do not replace or supersede EPA's 1988 national recommended criteria for aluminum in ambient water.

DATES: Comments must be received on or before September 26, 2017.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OW-2017-0260 to the *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the

⁴ The Council on Environmental Quality regulations addressing cooperating agency responsibilities are at Title 40, Code of Federal Regulations, Part 1501.6.

⁵ The Advisory Council on Historic Preservation's regulations are at Title 36, Code of Federal Regulations, Part 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places.

official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT:

Diana Eignor, Health and Ecological Criteria Division, Office of Water (Mail Code 4304T), Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone: (202) 566-1143; or email: eignor.diana@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. How can I get copies of this document and other related information?

1. *Docket.* EPA has established a docket for this action under Docket ID No. EPA-HQ-OW-2017-0260. Publicly available docket materials are available

either electronically through www.regulations.gov or in hard copy at the Water Docket in the EPA Docket Center, (EPA/DC) EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the Water Docket is (202) 566-2426.

2. *Electronic Access.* You may access this **Federal Register** document electronically from the Government Printing Office under the “**Federal Register**” listings FDSys (<http://www.gpo.gov/fdsys/browse/collection.action?collectionCode=FR>).

II. What is Aluminum and how does it affect aquatic life?

Aluminum is found in most soils and rocks and is the third most abundant element and the most common metal in the earth’s crust. Aluminum can enter the water via natural processes, like weathering of rocks. Aluminum is also released to water by mining, industrial processes using aluminum, and waste water treated with alum, an aluminum compound. Aluminum is considered a

non-essential metal because fish and other aquatic life do not need it to function. Elevated levels of aluminum can affect some species ability to regulate ions and inhibit respiratory functions. Aquatic plants are generally less sensitive to aluminum than fish and other aquatic life.

III. What are EPA’s updated recommended levels of aluminum in freshwater?

The recommended level of aluminum in freshwater depends on a site’s water quality parameters. Studies have shown that three water chemistry parameters, pH, dissolved organic carbon (DOC), and hardness, can affect the toxicity of aluminum by affecting the bioavailability of aluminum in the water to aquatic species. Unlike the fixed criteria values in EPA’s 1988 criteria document, these updated draft criteria use a Multiple Linear Regression (MLR) model to normalize the data, and the resulting criteria are based on site pH, DOC, and hardness. This allows users to develop site-specific aluminum criteria for fresh waters that appropriately reflect water quality parameters. See Table 1 for a comparison of EPA’s currently recommended and updated draft criteria values.

Table 1: 2017 Draft Aluminum Aquatic Life Criteria Compared to Current 1988 Criteria^a

Version	Freshwater Acute (1 day, total aluminum)	Freshwater Chronic (4-day, total aluminum)
2017 Draft AWQC Criteria (MLR normalized to pH = 7, hardness = 100 mg/L, DOC = 1 mg/L)	1,400 µg/L	390 µg/L
1988 AWQC Criteria (pH 6.5 – 9.0, across all hardness and DOC ranges)	750 µg/L	87 µg/L

^a Values are recommended not to be exceeded more than once every three years on average.

Note: Values will be different under differing water chemistry conditions as identified in this document.

IV. What are section 304(a) water quality criteria?

Section 304(a) water quality criteria are recommendations developed by EPA under authority of section 304(a) of the Clean Water Act based on the latest scientific information which examines the effect of a particular constituent concentration on an aquatic species and/or human health.

Section 304(a)(1) of the Clean Water Act directs the EPA to develop and publish and, from time to time, revise criteria for water quality accurately reflecting the latest scientific knowledge. Water quality criteria

developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

Section 304(a) criteria provide guidance to states and authorized tribes in adopting water quality standards that ultimately provide a basis for controlling discharges of pollutants. The criteria also provide guidance that EPA

considers when promulgating federal regulations under section 303(c) when such action is necessary. Under the Clean Water Act and its implementing regulations, states and authorized tribes are to adopt water quality criteria to protect designated uses (*e.g.*, aquatic life, recreational use). EPA’s water quality criteria recommendations are not regulations. Thus, EPA’s recommended criteria do not constitute legally binding requirements. States and authorized tribes may adopt other scientifically defensible water quality criteria that differ from these recommendations. As part of the WQS

triennial review process defined in section 303(c)(1) of the CWA, the states and authorized tribes are responsible for maintaining and revising WQS. Standards consist of designated uses, water quality criteria to protect those uses, a policy for antidegradation, and may include general policies for application and implementation. Section 303(c)(1) requires states and authorized tribes to review and modify, if appropriate, their WQS at least once every three years. States and authorized tribes must adopt water quality criteria that protect designated uses. Consistent with EPA's regulations at 40 CFR 131.11(a), protective criteria must be based on a sound scientific rationale and contain sufficient parameters or constituents to protect the designated uses. Criteria may be expressed in either narrative or numeric form. States and authorized tribes have four options when adopting water quality criteria for which EPA has published section 304(a) criteria. They may: (1) Establish numerical values based on recommended section 304(a) criteria; (2) Adopt section 304(a) criteria modified to reflect site-specific conditions; (3) Adopt criteria derived using other scientifically defensible methods; or (4) Establish narrative criteria where numeric criteria cannot be established or to supplement numeric criteria (40 CFR 131.11(b)).

V. Solicitation of Scientific Views

EPA is soliciting additional scientific views, data, and information regarding the science and technical approach used in the derivation of the draft criteria.

Dated: July 17, 2017.

Michael H. Shapiro,
Acting Assistant Administrator.

[FR Doc. 2017-15968 Filed 7-27-17; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[ER-FRL-9034-4]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564-7146 or <http://www.epa.gov/nepa>. Weekly receipt of Environmental Impact Statements (EISs) Filed 07/17/2017 Through 07/21/2017 Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other

Federal agencies. EPA's comment letters on EISs are available at: <http://www.epa.gov/compliance/nepa/eisdata.html>.

EIS No. 20170134, Final, FHWA, IL, Interstate 290 Eisenhower Expressway, Contact: Catherine A. Batey 217-492-4600, Under MAP-21 Section 1319, FHWA has issued a single FEIS and ROD. Therefore, the 30-day wait/review period under NEPA does not apply to this action.

EIS No. 20170135, Draft, NPS, WA, Olympic National Park Draft Mountain Goat Management Plan, Comment Period Ends: 09/26/2017, Contact: Christina Miller 360-565-3004.

EIS No. 20170136, Draft, BIA, WA, Confederated Tribes of the Colville Reservation Integrated Resource Management Plan 2015, Comment Period Ends: 09/11/2017, Contact: Anna Schmidt 503-231-6808.

EIS No. 20170137, Draft Supplement, Caltrans, CA, I-710 Corridor Project, Comment Period Ends: 09/22/2017, Contact: Jason Roach 213-897-0357.

EIS No. 20170138, Final, FERC, VA, Atlantic Coast Pipeline and Supply Header Project, Review Period Ends: 08/28/2017, Contact: Kevin Bowman 202-502-6287.

EIS No. 20170139, Final, FHWA, IL, US 30 from IL 136 to IL 40 Whiteside Co., Contact: Catherine A. Batey 217-492-4600, Under MAP-21 Section 1319, FHWA has issued a single FEIS and ROD. Therefore, the 30-day wait/review period under NEPA does not apply to this action.

EIS No. 20170140, Draft, USFS, WY, North Savery Project, Comment Period Ends: 09/12/2017, Contact: Paula Guenther 307-326-2507.

EIS No. 20170141, Draft, AFS, MT, Starry Goat, Comment Period Ends: 09/11/2017, Contact: Lisa Osborn 406-295-7558.

EIS No. 20170142, Adoption, Final, FAA, CA, ADOPTION—Land Acquisition and Airspace Establishment to Support Large-Scale Marine Air Ground Task Force Live-Fire and Maneuver Training at Marine Corps Air Ground Combat Center, Review Period Ends: 09/04/2017, Contact: Paula Miller 202-267-7378. The U.S. Department of Transportation's Federal Aviation Administration (FAA) has adopted the U.S. Department of Navy's FSEIS #20160327, filed 12/30/2016 with EPA. FAA was a cooperating agency on the project and recirculation of the document is not necessary under Section 1506.3(c) of the CEQ Regulations.

Amended Notices

EIS No. 20170106, Draft, NMFS, OR, Analyze Impacts of NOAA's National Marine Fisheries Service joining as a signatory to a new U.S. v. Oregon Management Agreement for the Years 2018-2027, Comment Period Ends: 08/21/2017, Contact: Jeromy Jording 360-753-9576. Revision to the FR Notice Published 06/23/2017; Extending the Comment Period from 08/07/2017 to 08/21/2017.

Dated: July 25, 2017.

Dawn Roberts,

Management Analyst, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2017-15966 Filed 7-27-17; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-9965-40-OA]

Notification of a Public Teleconference of the Chartered Clean Air Scientific Advisory Committee (CASAC) and the CASAC Secondary National Ambient Air Quality Standards Review Panel for Oxides of Nitrogen and Sulfur

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The EPA Science Advisory Board (SAB) Staff Office announces a public teleconference of the Chartered Clean Air Scientific Advisory Committee (CASAC) and CASAC Secondary National Ambient Air Quality Standards Review Panel for Oxides of Nitrogen and Sulfur to discuss the CASAC draft review of the EPA's *Integrated Science Assessment for Oxides of Nitrogen, Oxides of Sulfur, and Particulate Matter—Ecological Criteria (First External Review Draft—February 2017)*.

DATES: The teleconference will be held on August 31, 2017, from 1:00 p.m. to 5:00 p.m. (Eastern Time).

ADDRESSES: The public teleconference will be held by telephone only.

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing to obtain information concerning the public meeting may contact Dr. Thomas Armitage, Designated Federal Officer (DFO), EPA Science Advisory Board Staff Office (1400R), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; by telephone at (202) 564-2155 or at armitage.thomas@epa.gov. General information about the CASAC, as well as any updates concerning the meeting

announced in this notice, may be found on the CASAC Web page at <http://www.epa.gov/casac>.

SUPPLEMENTARY INFORMATION: The CASAC was established pursuant to the Clean Air Act (CAA) Amendments of 1977, codified at 42 U.S.C. 7409(d)(2), to review air quality criteria and National Ambient Air Quality Standards (NAAQS) and recommend any new NAAQS and revisions of existing criteria and NAAQS as may be appropriate. The CASAC is a Federal Advisory Committee chartered under the Federal Advisory Committee Act (FACA), 5 U.S.C., App. 2, Section 109(d)(1) of the CAA requires that the Agency periodically review and revise, as appropriate, the air quality criteria and the NAAQS for the six “criteria” air pollutants. EPA is currently reviewing the secondary (welfare-based) ambient air quality standards for oxides of nitrogen, oxides of sulfur, and particulate matter.

Pursuant to FACA and EPA policy, notice is hereby given that the Chartered CASAC and the CASAC Secondary National Ambient Air Quality Standards Review Panel for Oxides of Nitrogen and Sulfur will hold a public teleconference to discuss the draft CASAC review of the EPA’s *Integrated Science Assessment for Oxides of Nitrogen, Oxides of Sulfur, and Particulate Matter—Ecological Criteria (First External Review Draft—February 2017)*. The CASAC Secondary National Ambient Air Quality Standards Review Panel for Oxides of Nitrogen and Sulfur and the CASAC will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies.

Technical Contacts: Any technical questions concerning the *Integrated Science Assessment for Oxides of Nitrogen, Oxides of Sulfur, and Particulate Matter—Ecological Criteria (First External Review Draft—February 2017)* should be directed to Dr. Tara Greaver (greaver.tara@epa.gov), EPA Office of Research and Development.

Availability of Meeting Materials: Prior to the teleconference, the teleconference agenda, draft panel report, and other materials will be available on the CASAC Web page at <http://www.epa.gov/casac/>.

Procedures for Providing Public Input: Public comment for consideration by EPA’s federal advisory committees and panels has a different purpose from public comment provided to EPA program offices. Therefore, the process for submitting comments to a federal advisory committee is different from the process used to submit comments to an EPA program office.

Federal advisory committees and panels, including scientific advisory committees, provide independent advice to EPA. Members of the public can submit relevant comments on the topic of this advisory activity for the CASAC to consider as it develops advice for EPA. Input from the public to the CASAC will have the most impact if it provides specific scientific or technical information or analysis for CASAC panels to consider, or if it relates to the clarity or accuracy of the technical information. Members of the public wishing to provide comment should follow the instructions below to submit comments.

Oral Statements: In general, individuals or groups requesting an oral presentation on a public teleconference will be limited to three minutes. Each person making an oral statement should consider providing written comments as well as their oral statement so that the points presented orally can be expanded upon in writing. Interested parties should contact Dr. Thomas Armitage, DFO, in writing (preferably via email) at the contact information noted above by August 24, 2017, to be placed on the list of public speakers.

Written Statements: Written statements will be accepted throughout the advisory process; however, for timely consideration by CASAC members, statements should be supplied to the DFO (preferably via email) at the contact information noted above by August 24, 2017. It is the SAB Staff Office general policy to post written comments on the Web page for the advisory meeting or teleconference. Submitters are requested to provide an unsigned version of each document because the SAB Staff Office does not publish documents with signatures on its Web sites. Members of the public should be aware that their personal contact information, if included in any written comments, may be posted to the CASAC Web site. Copyrighted material will not be posted without explicit permission of the copyright holder.

Accessibility: For information on access or services for individuals with disabilities, please contact Dr. Thomas Armitage at (202) 564–2155 or armitage.thomas@epa.gov. To request accommodation of a disability, please contact Dr. Armitage preferably at least ten days prior to the teleconference to give EPA as much time as possible to process your request.

Dated: July 18, 2017.

Khanna Johnston,

Acting Deputy Director, EPA Science Advisory Board Staff Office.

[FR Doc. 2017–15972 Filed 7–27–17; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice to All Interested Parties of the Termination of The Receivership of 10383—BankMeridian, N.A. Columbia, South Carolina

Notice is hereby given that the Federal Deposit Insurance Corporation (FDIC) as Receiver for BankMeridian, N.A., Columbia, South Carolina (“the Receiver”) intends to terminate its receivership for said institution. The FDIC was appointed Receiver of BankMeridian, N.A. on July 29, 2011. The liquidation of the receivership assets has been completed. To the extent permitted by available funds and in accordance with law, the Receiver will be making a final dividend payment to proven creditors.

Based upon the foregoing, the Receiver has determined that the continued existence of the receivership will serve no useful purpose. Consequently, notice is given that the receivership shall be terminated, to be effective no sooner than thirty days after the date of this notice. If any person wishes to comment concerning the termination of the receivership, such comment must be made in writing and sent within thirty days of the date of this notice to: Federal Deposit Insurance Corporation, Division of Resolutions and Receiverships, Attention: Receivership Oversight Department 34.6, 1601 Bryan Street, Dallas, TX 75201.

No comments concerning the termination of this receivership will be considered which are not sent within this time frame.

Dated: July 24, 2017.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2017–15896 Filed 7–27–17; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice to All Interested Parties of the Termination of the Receivership of 10422—Patriot Bank Minnesota, Forest Lake, Minnesota

Notice is hereby given that the Federal Deposit Insurance Corporation (“FDIC”) as Receiver for Patriot Bank Minnesota, Forest Lake, Minnesota (“the Receiver”) intends to terminate its receivership for said institution. The FDIC was appointed receiver of Patriot Bank Minnesota on January 27, 2012. The liquidation of the receivership assets has been completed. To the extent permitted by available funds and in accordance with law, the Receiver will be making a final dividend payment to proven creditors.

Based upon the foregoing, the Receiver has determined that the continued existence of the receivership will serve no useful purpose. Consequently, notice is given that the receivership shall be terminated, to be effective no sooner than thirty days after the date of this Notice. If any person wishes to comment concerning the termination of the receivership, such comment must be made in writing and sent within thirty days of the date of this Notice to: Federal Deposit Insurance Corporation, Division of Resolutions and Receiverships, Attention: Receivership Oversight Department 34.6, 1601 Bryan Street, Dallas, TX 75201.

No comments concerning the termination of this receivership will be considered which are not sent within this time frame.

Dated: July 24, 2017.

Federal Deposit Insurance Corporation.

Robert E. Feldman,
Executive Secretary.

[FR Doc. 2017–15897 Filed 7–27–17; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL RESERVE SYSTEM

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice, request for comment.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) invites comment on a proposal to extend for three years, with revision, the Application for Employment with the Board of Governors of the Federal Reserve System (FR 28 and FR 28i; OMB

No. 7100–0181). On June 15, 1984, the Office of Management and Budget (OMB) delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve of and assign OMB control numbers to collection of information requests and requirements conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

DATES: Comments must be submitted on or before September 26, 2017.

ADDRESSES: You may submit comments, identified by *FR 28*, *FR 28s*, or *FR 28i* by any of the following methods:

- *Agency Web site:* <http://www.federalreserve.gov>. Follow the instructions for submitting comments at <http://www.federalreserve.gov/apps/foia/proposedregs.aspx>.
- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Email:* regs.comments@federalreserve.gov. Include OMB number in the subject line of the message.
- *Fax:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW., Washington, DC 20551.

All public comments are available from the Board’s Web site at <http://www.federalreserve.gov/apps/foia/proposedregs.aspx> as submitted, unless modified for technical reasons.

Accordingly, your comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper form in Room 3515, 1801 K Street (between 18th and 19th Streets NW.) Washington, DC 20006 between 9:00 a.m. and 5:00 p.m. on weekdays.

Additionally, commenters may send a copy of their comments to the OMB Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW., Washington, DC 20503 or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: A copy of the PRA OMB submission, including the proposed reporting form and instructions, supporting statement, and other documentation will be placed into OMB’s public docket files, once approved. These documents will also be made available on the Federal Reserve

Board’s public Web site at: <http://www.federalreserve.gov/apps/reportforms/review.aspx> or may be requested from the agency clearance officer, whose name appears below.

Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551 (202) 452–3829. Telecommunications Device for the Deaf (TDD) users may contact (202) 263–4869, Board of Governors of the Federal Reserve System, Washington, DC 20551.

SUPPLEMENTARY INFORMATION:

Request for Comment on Information Collection Proposal

The Board invites public comment on the following information collection, which is being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

- a. Whether the proposed collection of information is necessary for the proper performance of the Federal Reserve’s functions; including whether the information has practical utility;
- b. The accuracy of the Federal Reserve’s estimate of the burden of the proposed 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;
- d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and
- e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Federal Reserve should modify the proposed revisions prior to giving final approval.

Proposal To Approve Under OMB Delegated Authority the Extension for Three Years, With Revision, of the Following Report

Report title: Application for Employment with the Board of Governors of the Federal Reserve System.

Agency form number: FR 28, FR 28s, FR 28i.

OMB control number: 7100–0181.

Frequency: As needed.

Respondents: Individuals.

Estimated number of respondents: FR 28: 3,500, FR 28s: 2,000, FR 28i: 300.

Estimated average hours per response: FR 28: 1 hour, FR 28s: 1 minute, FR 28i: 15 minutes.

Estimated annual burden hours: FR 28: 3,500 hours, FR 28s: 33 hours, FR 28i: 75 hours, Total: 3,608 hours.

General Description of Report: The Application for Employment with the Board of Governors of the Federal Reserve System (Application) collects information to determine the qualifications and availability of applicants for employment with the Board of Governors of the Federal Reserve System (Board). The FR 28 collects information on education and training, employment record, military service record, and other information since the time the applicant left high school. Included with the FR 28 are two supplemental questionnaires: (1) The Applicant's Voluntary Self-Identification Form (FR 28s), which collects information on the applicant's gender and ethnic group and (2) The Research Assistant Candidate Survey of Interests (FR 28i), which collects information from candidates applying for Research Assistant (RA) positions on their level of interest in economics and related areas. The Board receives approximately 3,500 applications per year, both solicited and unsolicited, from members of the public who would like to be considered for employment at the Board. Since the applicant is usually either hired by the Board or finds other employment within the two years that the Board retains the Application, the applicant generally files the Application once.

The Application is comprised of eight sections: Background, Education and Training, Employment Record, Military Service Record, References, General, Remarks, and Notes. The first six sections collect information on specific aspects of the applicant's qualifications. The Background section collects name, address, telephone, and citizenship information and the position for which the applicant is applying. The Education and Training section collects detailed information on the applicant's educational history and skills set. The Employment Record section collects a chronological summary of work experience. The Military Service Record section collects information on service branch, rank, duties, and discharge. The References section collects information on three references. The General section collects information on criminal records, discharge from employment, willingness to travel, and relations to or acquaintances with Board staff or officers and directors of financial institutions. The Remarks section provides the applicant an opportunity to

provide further information regarding his or her qualifications. The Notes section explains what is required of the applicant prior to an interview and what may be required of the applicant if he or she is offered a position (for example, transcripts, medical examination, or drug test).

The FR 28s is comprised of four sections: (1) Name and gender, in which applicants are asked to check the box that corresponds to their gender or check "I do not wish to disclose", (2) position for which the applicant is applying, (3) ethnicity self-identification, in which applicants are asked to choose between Hispanic or Latino or Not Hispanic or Latino, or "I do not wish to disclose," and (4) race self-identification, in which applicants are asked to choose one or more among American Indian or Alaskan Native, Asian, Black or African-American, Native Hawaiian or Other Pacific Islander, White, or "I do not wish to disclose." The Board uses this information to comply with federal equal employment opportunity (EEO) recordkeeping and reporting requirements, other legal requirements, and as an input to its self-analysis of hiring practices. Information collected on the FR 28s has no bearing on the determination of an applicant's job-related qualifications and completion of the self-identification form is voluntary.

The FR 28i is comprised of three sections in which research assistant candidates are asked to rate their level of interest in categories of economics and related research areas, experience with various software packages and statistical programming languages, and interest in pursuing educational opportunities after leaving the Board. The FR 28i helps to streamline the recruitment process.

Proposed revisions: The Board proposes four changes to the FR 28 form: (1) Adding fields in the employment history section for job type, shift, employee status, and desired compensation; (2) adding fields in the education and training section for issue and expiration date for certifications and professional licenses; (3) adding fields in the references section for relationship, type, and length of relationship with the reference; and (4) adding fields in the submission section to allow for withdrawal of the application and a request for the applicant to provide a reason for withdrawal.

The Board proposes to revise the FR 28i questionnaire by adding a section to allow an open-ended response by applicants to describe how they've demonstrated attributes that are

displayed by successful research assistants in the Economics Divisions.

Legal authorization and confidentiality: The Board's Legal Division has determined that the Application (including the two supplemental questionnaires) is required to obtain the benefit of Board employment. It is authorized pursuant to sections 10(4) and 11(1) of the Federal Reserve Act, which provide the Federal Reserve Board broad authority over employment of staff. (12 U.S.C. 244 and 248(l)). Information provided on the Application (including the two supplemental questionnaires) will be kept confidential under exemption (b)(6) of the Freedom of Information Act (FOIA) to the extent that the disclosure of information "would constitute a clearly unwarranted invasion of personal privacy." (5 U.S.C. 552(b)(6)). However, the release of information such as the educational and professional qualifications of applicants would not likely constitute a clearly unwarranted invasion of personal privacy and would not be kept confidential.

Board of Governors of the Federal Reserve System, July 24, 2017.

Ann E. Misback,

Secretary of the Board.

[FR Doc. 2017-15875 Filed 7-27-17; 8:45 am]

BILLING CODE 6210-01-P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than August 14, 2017.

A. Federal Reserve Bank of Richmond (Adam M. Drimer, Assistant Vice President) 701 East Byrd Street, Richmond, Virginia 23261-4528. Comments can also be sent electronically to *Comments.applications@rich.frb.org*:

1. *David M. Thomas, Morgantown, West Virginia, to individually retain voting shares, and by the Brian F. Thomas Revocable Trust—2015, the Mary F. Thomas Trust, Staci Thomas, Morgantown, West Virginia, Sandra Thomas, Morgantown, West Virginia, and Kendall Thomas, Bruceton Mills, West Virginia;* to join the previously approved Thomas family control group, and thereby acquire voting shares of State Bancorp, Inc. and thereby acquire voting shares of Clear Mountain Bank, both of Bruceton Mills, West Virginia.

Board of Governors of the Federal Reserve System, July 25, 2017.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2017-15967 Filed 7-27-17; 8:45 am]

BILLING CODE 6210-01-P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000-0134; Docket 2017-0053; Sequence 4]

Submission for OMB Review; Environmentally Sound Products

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for public comments regarding an extension to an existing OMB clearance.

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 concerning environmentally sound products. A notice published in the **Federal Register** at 82 FR 20339 on June 30, 2017. No comments were received.

DATES: Submit comments on or before August 28, 2017.

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:

- *Regulations.gov:* <http://www.regulations.gov>. Submit comments via the Federal eRulemaking portal by searching the OMB control number 9000-0134. Select the link “Comment Now” that corresponds with “Information Collection 9000-0134, Environmentally Sound Products”. Follow the instructions provided on the screen. Please include your name, company name (if any), and “Information Collection 9000-0134, Environmentally Sound Products” on your attached document.

- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: Ms. Jo Ann Sosa/IC 9000-0134, Environmentally Sound Products.

Instructions: Please submit comments only and cite Information Collection 9000-0134, Environmentally Sound Products, 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. Charles Gray, Procurement Analyst, Governmentwide Acquisition Policy, GSA, 703-795-6328 or charles.gray@gsa.gov.

SUPPLEMENTARY INFORMATION:

A. Purpose

OMB clearance 9000-0134 supports the information collection requirement contained in 52.223-9, Estimate of Percentage of Recovered Material Content for EPA-designated Items. Section 6002 of the Resource Conservation and Recovery Act (RCRA), Public Law 94-580, (42 U.S.C. 6962), requires Federal agencies to develop affirmative procurement programs to ensure that items composed of recovered materials will be purchased to the maximum extent practicable. An agency's affirmative procurement program must include: (1) A recovered materials preference program and an agency promotion program for the preference program; (2) a program for requiring estimates of the total percentage of recovered materials used in the performance of a contract, certification of minimum recovered material content used, and where appropriate and reasonable, verification procedures for estimates and

certifications; and (3) annual review and monitoring of the effectiveness of an agency's affirmative procurement program.

For items the Environmental Protection Agency (EPA) has designated as produced or that can be produced from recovered material, agencies are required to track the percentage of recovered material content used during contract performance. This requirement applies whenever an acquisition sets forth minimum percentages of recovered materials; when the price of the item exceeds \$10,000; or when the aggregate amount paid for the item or functionally equivalent items in the preceding fiscal year was \$10,000 or more.

Pursuant to FAR clause 52.223-9, when the contract requires the delivery of or use of an EPA-designated item, contractors shall report the estimated percentage of total recovered material content delivered or used, at contract completion. The clause is included in solicitations and contracts exceeding \$150,000, except for acquisitions of commercially-available, off-the-shelf (COTS) items.

B. Annual Reporting Burden

Respondents: 1,047.

Responses per Respondent: 1.5.

Annual Responses: 1,571.

Hours per Response: .50.

Total Burden Hours: 785.

C. Public Comments

Public Comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the Federal Acquisition Regulation (FAR), and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals:

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. 9000-0134, Environmentally Sound Products, in all correspondence.

Dated: July 25, 2017.

Lorin S. Curit,

Director, Federal Acquisition Policy Division,
Office of Governmentwide Acquisition Policy,
Office of Acquisition Policy, Office of
Governmentwide Policy.

[FR Doc. 2017-15931 Filed 7-27-17; 8:45 am]

BILLING CODE 6820-EP-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research
and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the
intention of the Agency for Healthcare
Research and Quality (AHRQ) to request
that the Office of Management and
Budget (OMB) approve the proposed
information collection project: “*Generic
Clearance for Questionnaire and Data
Collection Testing, Evaluation, and
Research for the Agency for Healthcare
Research and Quality.*”

This proposed information collection
was previously published in the **Federal
Register** on April 28, 2017, and allowed
60 days for public comment. No
substantive comments were received.
The purpose of this notice is to allow an
additional 30 days for public comment.

DATES: Comments on this notice must be
received by August 28, 2017.

ADDRESSES: Written comments should
be submitted to: AHRQ’s OMB Desk
Officer by fax at (202) 395-6974
(attention: AHRQ’s desk officer) or by
email at OIRA_submission@omb.eop.gov (attention: AHRQ’s desk
officer).

FOR FURTHER INFORMATION CONTACT:
Doris Lefkowitz, AHRQ Reports
Clearance Officer, (301) 427-1477, or by
email at doris.lefkowitz@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

*Generic Clearance for Questionnaire
and Data Collection Testing, Evaluation,
and Research for the Agency for
Healthcare Research and Quality*

In accordance with the Paperwork
Reduction Act, 44 U.S.C. 3501-3520,
AHRQ invites the public to comment on
this proposed information collection.
The Agency for Healthcare Research and

Quality (AHRQ) requests that the Office
of Management and Budget (OMB)
reapprove generic pre-testing Clearance
0935-0124 for three years to facilitate
AHRQ’s efforts to (1) employ
evaluation-type methods and techniques
to improve AHRQ’s current data
collection and estimation procedures,
(2) develop new collections and
procedures, including toolkits, and (3)
revise existing collections and
procedures. AHRQ believes that
developing, testing, and evaluating data
collection and estimation procedures
using survey methods and other
techniques in anticipation of Agency-
sponsored studies can improve its
information collection efforts, and the
products it develops and allow AHRQ to
be more responsive to fast-changing
developments in the health care
research. AHRQ uses techniques to
simplify data collection and estimation
procedures, reduce respondent burden,
and improve efficiencies to meet the
needs of individuals and small business
respondents who may have reduced
budgets and staff.

This clearance request is limited to
research on data collection, toolkit
development, and estimation
procedures and reports and does not
extend to the collection of data for
public release or policy formation. The
current Clearance (0935-0124) was
granted on November 12, 2014, and
expires on November 30, 2017.

This generic clearance will allow
AHRQ to draft and test toolkits, survey
instruments and other data collection
and estimation procedures more quickly
and with greater lead time, thereby
managing project time more efficiently
and improving the quality of the data
AHRQ collects. In some instances, the
ability to test and evaluate toolkits, data
collection and estimation procedures in
anticipation of work or early in a project
may result in the decision not to
proceed with additional activities,
which could save both public and
private resources and eliminate
respondent burden.

This generic clearance will facilitate
AHRQ’s response to a changing
environment. Many of the tools AHRQ
develops are made available to the
private sector to assist in improving
health care quality. The health and
health care environment changes
rapidly and requires a quick response
from AHRQ to provide refined tools.

These preliminary research activities
will not be used by AHRQ to regulate
or sanction its customers. They will be
entirely voluntary and the

confidentiality of respondents and their
responses will be preserved. Proposed
information collections submitted under
this generic clearance will be submitted
for review by OMB with a response
expected in 14 days.

Method of Collection

The information collected through
preliminary research activities under
this generic clearance will be used by
AHRQ to employ techniques to (1)
improve AHRQ’s current data collection
and estimation procedures, (2) develop
new collections and procedures,
including toolkits, and (3) revise
existing collections and procedures in
anticipation or in response to changes in
the health or health care. The end result
will be improvement in AHRQ’s data
collections and procedures and the
quality of data collected, a reduction or
minimization of respondent burden,
increased agency efficiency, and
improved responsiveness to the public.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated burden
hours, over the full 3 years of this
clearance, for the respondents’ time to
participate in the research activities that
may be conducted under this generic
clearance. Mail surveys will be
conducted with about 6,000 persons
(2,000 per year for 3 years) and are
estimated to average 20 minutes. Mail
surveys may also be sent to respondents
via email, and may include a telephone
non-response follow-up. Telephone
non-response follow-up for mailed
surveys is not counted as a telephone
survey in Exhibit 1. Not more than 600
persons, over 3 years, will participate in
telephone surveys that will take about
40 minutes. Web-based surveys will be
conducted with no more than 3,000
persons and will require no more than
10 minutes to complete. About 1,500
persons will participate in focus groups
which may last up to two hours, while
in-person interviews will be conducted
with 600 persons and will take about 50
minutes. Automated data collection will
be conducted for about 1,500 persons
and could take up to 1 hour. Cognitive
testing will be conducted with about
600 persons and is estimated to take 1½
hours to complete. The total burden
over 3 years is estimated to be 8,900
hours (about 2,967 hours per year).

Exhibit 2 shows the estimated cost
burden over 3 years, based on the
respondent’s time to participate in these
research activities. The total cost burden
is estimated to be \$338,734.

EXHIBIT 1—ESTIMATED BURDEN HOURS OVER 3 YEARS

Type of information collection	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Mail/email *	6,000	1	20/60	2,000
Telephone	600	1	40/60	400
Web-based	3,000	1	10/60	500
Focus Groups	1,500	1	2.0	3,000
In-person	600	1	1.0	600
Automated **	1,500	1	1.0	1,500
Cognitive Testing ***	600	1	1.5	900
Totals	13,800	na	na	8,900

* May include telephone non-response follow-up in which case the burden will not change.

** May include testing of database software, CAPI software or other automated technologies.

*** May include cognitive interviews for questionnaire or toolkit development, or “think aloud” testing of prototype Web sites.

EXHIBIT 2—ESTIMATED COST BURDEN OVER 3 YEARS

Type of information collection	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Mail/email	6,000	2,000	\$38.06	\$76,120
Telephone	600	400	38.06	15,224
Web-based	3,000	500	38.06	19,030
Focus Groups	1,500	3,000	38.06	114,180
In-person	600	600	38.06	22,836
Automated	1,500	1,500	38.06	57,090
Cognitive Testing	600	900	38.06	34,254
Totals	13,800	8,900	na	338,734

* Based upon the average wages for 29–000 (Healthcare Practitioner and Technical Occupations), “National Compensation Survey: Occupational Wages in the United States, May 2016,” U.S. Department of Labor, Bureau of Labor Statistics https://www.bls.gov/oes/current/oes_nat.htm#29-0000.

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ’s information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ’s estimate of burden (including hours and costs) of the proposed collection(s) 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 upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency’s subsequent request for OMB approval of the proposed information collection. All

comments will become a matter of public record.

Sharon B. Arnold,
Deputy Director.

[FR Doc. 2017–15883 Filed 7–27–17; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) reapprove the proposed information collection project: “Medical Expenditure Panel Survey—Insurance Component.”

This proposed information collection was previously published in the **Federal Register** on April 28, 2017, and allowed

60 days for public comment. No substantive comments were received; however changes have been made to the burden estimates in Exhibit 1, resulting in an increase of 1,316 burden hours. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by August 28, 2017.

ADDRESSES: Written comments should be submitted to: AHRQ’s OMB Desk Officer by fax at (202) 395–6974 (attention: AHRQ’s desk officer) or by email at OIRA_submission@omb.eop.gov (attention: AHRQ’s desk officer).

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at doris.lefkowitz@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project*Medical Expenditure Panel Survey—Insurance Component*

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection. Employer-sponsored health insurance is the source of coverage for 84.4 million current and former workers, plus many of their family members, and is a cornerstone of the U.S. health care system. The Medical Expenditure Panel Survey—Insurance Component (MEPS–IC) measures the extent, cost, and coverage of employer-sponsored health insurance on an annual basis. These statistics for private industry are produced at the National, State, and sub-State (metropolitan area) level. Statistics are also produced for State and Local governments.

This research has the following goals:

(1) Provide data for Federal policymakers evaluating the effects of National and State health care reforms.

(2) Provide descriptive data on the current employer-sponsored health insurance system and data for modeling the differential impacts of proposed health policy initiatives.

(3) Supply critical State and National estimates of health insurance spending for the National Health Accounts and Gross Domestic Product.

The MEPS–IC is conducted pursuant to AHRQ's statutory authority to conduct surveys to collect data on the cost, use and quality of health care, including types and costs of private insurance, 42 U.S.C. 299b–2(a), and to

conduct research on health care, 42 U.S.C. 299a.

Method of Collection

To achieve the goals of this project, following data collections will be implemented for both private sector and state and local government employers:

(1) *Pre-screener Questionnaire*—The purpose of the Pre-screener Questionnaire, which is collected via telephone, varies depending on the insurance status of the establishment contacted. Establishment is defined as a single, physical location in the private sector and a governmental unit in state and local governments. For establishments that do not offer health insurance to their employees, the Pre-screener Questionnaire is used to collect basic information, such as number of employees. For establishments that do offer health insurance, the Pre-screener Questionnaire collects contact name and address information for the person in the establishment best equipped to complete the full questionnaire.

(2) *Establishment Questionnaire*—The purpose of the mailed Establishment Questionnaire is to obtain general information from employers that provide health insurance to their employees, including total active enrollment in health insurance, other employee benefits, demographic characteristics of employees, and retiree health insurance.

(3) *Plan Questionnaire*—The purpose of the mailed Plan Questionnaire is to collect plan-specific information on each plan (up to four plans) offered by establishments. This questionnaire

obtains information on total premiums, employer and employee contributions to the premium, and plan enrollment for each type of coverage offered—single, employee-plus-one, and family—within a plan. It also asks for information on deductibles, copays, and other plan characteristics.

The primary objective of the MEPS–IC is to collect information on employer-sponsored health insurance. Such information is needed in order to provide the tools for Federal, State, and academic researchers to evaluate current and proposed health policies and to support the production of important statistical measures for other Federal agencies.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondent's time to participate in the MEPS–IC. The Pre-screener questionnaire will be completed by 30,041 respondents and takes 5 minutes to complete. The Establishment questionnaire will be completed by 25,914 respondents and takes 23 minutes to complete. The Plan questionnaire will be completed by 22,943 respondents and will require an average of 2.5 responses per respondent. Each Plan questionnaire takes 11 minutes to complete. The total annualized burden hours are estimated to be 22,952 hours.

Exhibit 2 shows the estimated annualized cost burden associated with the respondents' time to participate in this data collection. The annualized cost burden is estimated to be \$733,776.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS FOR THE 2018–2019 MEPS–IC

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Prescreener Questionnaire	30,041	1	5/60	2,503
Establishment Questionnaire	25,914	1	* 23/60	9,934
Plan Questionnaire	22,943	2.5	11/60	10,515
Total	78,898	na	na	22,952

* The burden estimate printed on the establishment questionnaire is 45 minutes which includes the burden estimate for completing the establishment questionnaire and two plan questionnaires (on average, each establishment completes 2.5 plan questionnaires). The establishment and plan questionnaires are sent to the respondent as a package and are completed by the respondent at the same time.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN FOR THE 2018–2019 MEPS–IC

Form name	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Prescreener Questionnaire	30,041	2,503	31.97	\$80,021
Establishment Questionnaire	25,914	9,934	31.97	317,590
Plan Questionnaire	22,943	10,515	31.97	336,165

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN FOR THE 2018–2019 MEPS–IC—Continued

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Total	78,898	22,952	na	733,776

*Based upon the mean hourly wage for Compensation, Benefits, and Job Analysis Specialists occupation code 13–1141, at <https://www.bls.gov/oes/current/oes131141.htm> (U.S. Department of Labor, Bureau of Labor Statistics.)

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) 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 upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Sharon B. Arnold,
Deputy Director.

[FR Doc. 2017–15884 Filed 7–27–17; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: “*The AHRQ Safety Program for Improving Surgical Care and Recovery*.”

This proposed information collection was previously published in the **Federal Register** titled “*The AHRQ Safety Program for Enhancing Surgical Care and Recovery*,” on May 18, 2017 and allowed 60 days for public comment. AHRQ did not receive any substantive comments. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by August 28, 2017.

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395–6974 (attention: AHRQ's desk officer) or by email at OIRA_submission@omb.eop.gov (attention: AHRQ's desk officer).

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at doris.lefkowitz@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection. The AHRQ Safety Program for Improving Surgical Care and Recovery is a quality improvement project that aims to provide technical assistance to hospitals to help them implement evidence-based practices to improve outcomes and prevent complications among patients who undergo surgery. Enhanced recovery pathways are a constellation of preoperative, intraoperative, and postoperative practices that decrease complications and accelerate recovery. A number of studies and meta-analyses have demonstrated successful results. In order to facilitate broader adoption of these evidence-based practices among U.S. hospitals, this AHRQ project will adapt the Comprehensive Unit-based Safety Program (CUSP), which has been demonstrated to be an effective approach to reducing other patient harms, to enhanced recovery of surgical patients. The approach uses a combination of clinical and cultural (i.e., technical and adaptive) intervention components which include

promoting leadership and frontline staff engagement, close teamwork among surgeons, anesthesia providers, and nurses, as well as enhancing patient communication and engagement. Interested hospitals will voluntarily participate.

This project has the following goals:

- Improve outcomes of surgical patients by disseminating and supporting implementation of evidence-based enhanced recovery practices within the CUSP framework.
- Develop a bundle of technical and adaptive interventions and associated tools and educational materials to support implementation.
- Provide technical assistance and training to hospitals for implementing enhanced recovery practices.
- Assess the adoption, and evaluate the effectiveness of, the intervention among the participating hospitals.

This project is being conducted by AHRQ through its contractor Johns Hopkins University; with subcontractors Westat, and the American College of Surgeons. The *AHRQ Safety Program for Improving Surgical Care and Recovery* is being undertaken pursuant to AHRQ's mission to enhance the quality, appropriateness, and effectiveness of health services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health systems practices, including the prevention of diseases and other health conditions. 42 U.S.C. 299.

Method of Collection

To achieve the goals of this project the following data collections will be implemented:

(1) *Safety Culture Survey*. Hospitals will assess the impact of participation in the project on perioperative safety culture by having their staff members who will be part of the enhanced recovery program complete a survey adapted from the AHRQ Surveys on Patient Safety Culture (SOPS) at the beginning and end of the program. The hospital's enhanced recovery project team will receive their survey results and then debrief their staff on their safety culture and identify opportunities for further improvement. The national

project team will provide technical assistance for this effort. Participating hospitals will promote awareness of the survey among their staff, coordinate implementation of the survey, encourage and provide staff the time to complete the survey, and organize a local debrief of the reports of their hospital's results. The national project team will assist this effort by providing an electronic portal for hospital staff to anonymously complete the survey and by analyzing the data and sending a report to the hospital. Data will also be analyzed in aggregate across all participating hospitals to evaluate the impact of the overall quality improvement effort on measured safety culture.

(2) *Patient Experience Survey.* Hospitals will also assess the impact of participation in the project on patients' experience with care. This will be done via administration of a patient experience survey to patients discharged after a qualifying surgery. Patients will receive a pre-implementation assessment of patient experience after a qualifying surgery and a post-implementation assessment of patient experience will be administered to patients who were treated the enhanced recovery program at participating hospitals. The survey will be administered by the national project team. Hospitals will provide patient contact information to the project team after execution of a data use agreement. This information will be

provided to the national project team to send the survey to patients on behalf of the hospital. The national project team will provide a summative report to each hospital with the hospital's results to promote additional local quality improvement work. Data will also be analyzed in aggregate across all participating hospitals to evaluate the impact of the overall quality improvement effort on patient experience of care.

(3) *Readiness and Implementation Assessments: Semi-structured qualitative interviews.* Semi-structured qualitative interviews will be conducted with key stakeholders at participating hospitals (e.g., project leads, physician project champions, etc.). These include a readiness assessment conducted after a hospital's enrollment in the project and an implementation assessment conducted after a period of implementation. The readiness assessment will help identify which, if any, technical components of the enhanced surgical care and recovery intervention already exist at the hospital, project management and resources, clinician engagement, leadership engagement and potential barriers and facilitators to implementation. The implementation assessment will evaluate what elements of the enhanced recovery practices have been adopted, resources invested, team participation, major barriers (e.g., medications, equipment, trained personnel), and leadership

participation. These assessments will help identify training needs of hospitals and inform the national team's approach. In addition, the results will inform the national team's understanding of local adaptations of the intervention and the degree to which intervention fidelity impacts changes in outcomes.

(4) *Site visits.* Semi-structured site visits will be conducted at a subset of participating hospitals. Findings will help inform the national project implementation strategy. Information from these visits will be critical in understanding if and how team and/or leadership issues may affect implementation of enhanced recovery practices, including how this may differ across surgical services. Interviews will help uncover and clarify misalignments in roles, needed time and resources, best practices, and potential enablers of and barriers to enhanced surgical care and recovery implementation. Site visits will be conducted at approximately 4 hospitals per year, and each will be 1 day long. The types of hospital personnel anticipated being involved in part or all of the site visit include senior leadership, perioperative leadership, and patient safety and quality staff. Participating hospitals will receive a structured debriefing and brief summary report at the end of the one-day visit.

Estimated Annual Respondent Burden

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Safety culture survey	12,000	1	0.25	3,000
Patient experience survey	1,800	1	0.37	666
Readiness and Implementation assessment	720	1	1	720
Site visits	40	1	8	320
Total	14,560	N/A	N/A	4,706

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Safety culture survey	6,000	1,500	^a \$101.04	\$151,560
Safety culture survey	6,000	1,500	^b 34.70	52,050
Patient experience survey	1,800	666	^d 23.86	15,891
Readiness and Implementation assessment	360	360	^a 101.04	36,374
Readiness and Implementation assessment	360	360	^c 52.58	18,929
Site visits	20	160	^a 101.04	16,166
Site Visits	20	160	^c 52.58	8,413
Total	14,560	4,706	N/A	299,383

National Compensation Survey: Occupational wages in the United States May 2016 "U.S. Department of Labor, Bureau of Labor Statistics:" http://www.bls.gov/oes/current/oes_stru.htm.

^a Based on the mean wages for 29–1060 Physicians and Surgeons.

^b Based on the mean wages for 29–1141 Registered Nurse.

^c Based on the mean wages for 11–9111 Medical and Health Services Managers.

^d Based on the mean wages for 00–0000 All Occupations.

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) 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 upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Sharon B. Arnold,
Deputy Director.

[FR Doc. 2017–15885 Filed 7–27–17; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project “*Expanding the Comprehensive Unit-based Safety Program (CUSP) to Reduce Central Line-Associated Blood Stream Infections (CLABSI) and Catheter-Associated Urinary Tract Infections (CAUTI) in Intensive Care Units (ICU) with Persistently Elevated Infection Rates.*”

DATES: Comments on this notice must be received by September 26, 2017.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at doris.lefkowitz@AHRQ.hhs.gov.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at doris.lefkowitz@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

Expanding the Comprehensive Unit-Based Safety Program (CUSP) To Reduce Central Line-Associated Blood Stream Infections (CLABSI) and Catheter-Associated Urinary Tract Infections (CAUTI) in Intensive Care Units (ICU) With Persistently Elevated Infection Rates

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection. Healthcare-associated infections, or HAIs, are a highly significant cause of illness and death for patients in the U.S. health care system. At any given time, HAIs affect one out of every 25 hospital inpatients. More than a million of these infections occur across our health care system every year, leading to significant patient harm and the annual loss of tens of thousands of lives, and costing billions of dollars each year. Some of the most prevalent HAIs include: Surgical site infections, catheter-associated urinary tract infections (CAUTI), central-line associated blood stream infections (CLABSI), and ventilator-associated pneumonia. It is estimated that CAUTIs affect approximately 250,000 hospital patients per year, and approximately 40,000 CLABSI cases occur annually with a mortality rate from 12 to 25 percent.

From 2008–2012, AHRQ supported the National Implementation of the Comprehensive Unit-Based Safety Program (CUSP) to Reduce Central Line-Associated Blood Stream Infections (under an ACTION contract with the Health Research and Educational Trust (HRET), in partnership with Johns Hopkins University and the Michigan Hospital Association. From 2011–2015, AHRQ expanded its CUSP efforts to

include the national implementation of CUSP for CAUTI in hospitals across the United States. This effort was carried out under an ACTION II contract with HRET, in partnership with Johns Hopkins University and the Michigan Hospital Association.

As part of the Department of Health and Human Services National Action Plan to Prevent Healthcare-Associated Infections, AHRQ has supported the implementation and adoption of the CUSP for CLABSI and CUSP for CAUTI, and is applying the principles and concepts that have been learned from these HAI reduction efforts to ICUs with persistently elevated infection rates.

Results of Implementation of CUSP for CLABSI and CAUTI

The nationwide CUSP for CLABSI project implemented CUSP with teams at more than 1,100 adult ICUs in 44 states over a 4-year period. ICUs participating in this project reduced the rate of CLABSIs nationally from 1.915 infections per 1,000 central line days to 1.133 infections per 1,000 line days, an overall reduction of 41 percent. However, not all ICUs performed equally well.

The CUSP for CAUTI project implemented CUSP in nine cohorts, representing over 1,600 hospital units in over 1,200 hospitals located across 40 states, the District of Columbia, and Puerto Rico. Inpatient CAUTI rates in non-ICUs were decreased by 30%. However, CAUTI rates in ICUs were not reduced significantly.

In other words, while the overall results of the implementation of CUSP for CLABSI and CUSP for CAUTI have shown remarkable progress, not all ICUs in the projects have achieved the intended rate reductions, nor have all ICUs participated in the two projects. Moreover, a significant number of institutions and ICUs continue to have persistently elevated infection rates. There are institutions that have varying rates of infections within the same institution, indicating that infection control is often a unit-based issue.

In sum, despite the significant overall reductions in CLABSI and CAUTI rates that have been achieved in these two projects, there is evidence that ICUs have generally faced challenges in reducing CAUTI rates, and that many hospitals still are not where they should be in CLABSI rates. Modified approaches and strategies for the CUSP intervention need to be developed and implemented to reach ICUs with

persistently elevated CLABSI and CAUTI rates and help them succeed in preventing these infections. To address this need, AHRQ will launch this project aimed at spreading nationally implementation of an adaptation of CUSP for CLABSI and CAUTI for ICUs with persistently elevated rates, optimizing the approach to maximize effectiveness, and further preventing these infections throughout the United States.

This project has the following goals:

- Reduce CLABSI and CAUTI in ICUs with persistently elevated rates.

- Revise and augment current CUSP training resources and materials for CUSP for CLABSI and CAUTI in ICUs with persistently elevated rates. The resulting toolkit will be intended for use in ICUs whose infection rates for either or both of these HAIs are persistently elevated compared to other ICUs.

- Recruit 450–600 ICUs with persistently elevated rates nationally to demonstrate the utility of applying a modified CUSP for CLABSI and CUSP for CAUTI during the performance period to reduce rates of CLABSI and CAUTI in these ICUs.

- Assess the adoption of the modified CUSP for CLABSI and CAUTI and evaluate the effectiveness of the intervention in the participating ICUs

This study is being conducted by AHRQ through its contractor, pursuant to AHRQ's statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of health care services and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

Method of Collection

To achieve the goals of this project the following data collections will be implemented:

(1) *ICU Assessment Tool*: The ICU assessment tool will be completed by the unit project team leader in collaboration with individuals with strong knowledge of current clinical and safety practices in the ICU, such as the ICU manager, infection preventionist, quality leader, clinical educator, or clinical nurse specialist. The purpose of this assessment is to understand current HAI prevention practices, policies, and procedures to tailor the educational program to meet the needs of the ICU. An assessment will be administered at the end of the program to monitor any changes in practices, policies, and procedures after program participation; the unit will receive an individualized report based on responses.

(2) *Team Checkup Tool*: The unit team members (such as the ICU manager, quality leader, clinical educator, or clinical nurse specialist) will complete one Team Check-up Tool every month during the project period. The information collected will be used for coaching assistance by the unit project team leader. This tool helps assess unit strengths and opportunities for improving unit processes, procedures, and safety culture. This will be accomplished by the following steps:

- Hold a short, recurring meeting with the team to complete this tool and review the results.
- Randomly select staff from the unit to answer questions 1–3. Staff selected should not exclusively include those completing this form.
- For statements where the 'No' or 'Don't Know' column is checked, review opportunities for improvement.

- Develop a Plan-Do-Study-Act (PDSA) plan and complete rapid cycles of improvement over the course of the month and reevaluate.

(3) *Site Visits*: State leads and clinical mentors will coordinate state-level, in-person site visits for 50 percent of participating hospital units. Site visits are an opportunity for state leads and clinical mentors to meet with ICU teams and their leadership to strengthen relationships, engage in open discussion about infection prevention, and facilitate unit-specific changes through action planning. Site visit evaluation is based on the Site Visit Guidance and Action Planning Template. State leads will submit an action planning report to the project Web site within one week of the visit.

This data collection effort will be part of a comprehensive evaluation strategy to assess the adoption of the Expansion of the Comprehensive Unit-Based Safety Program for CLABSI and CAUTI in ICUs with persistently elevated rates; measure the effectiveness of the interventions in the participating units; and evaluate the characteristics of teams that are associated with successful implementation and improvements in outcomes.

The evaluation of this data collection is largely foundational in nature as AHRQ seeks information on the implementation and effectiveness of the CUSP for CLABSI and CAUTI in ICUs with persistently elevated rates. The evaluation of the tools above will utilize a pre-post design, comparing practices, policies and procedures before and after participating in the program.

Estimated Annual Respondent Burden

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
ICU Assessment Tool	150	2	1.25	375
Team Checkup Tool	150	12	.2	360
Site Visits	75	1	4	300
Total	375	N/A	N/A	1,035

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
ICU Assessment Tool	150	375	^a \$52.58	\$19,718
Team Checkup Tool	150	360	^a \$52.58	18,929
Site Visits	75	75	^b \$27.87	2,090
		150	^c \$34.70	5,205
		37.5	^a \$52.58	1,972

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN—Continued

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
		37.5	^d 98.83	3,706
Total	375	1,035	N/A	\$51,620

National Compensation Survey: Occupational wages in the United States May 2016 "U.S. Department of Labor, Bureau of Labor Statistics:" http://www.bls.gov/oes/current/oes_stru.htm.

^aBased on the mean wages for 11–9111 *Medical and Health Services Managers*.

^bBased on the mean wages for 29–9099 *Miscellaneous Health Practitioners and Technical Workers: Healthcare Practitioners and Technical Workers, All Other*.

^cBased on the mean wages for 29–1141 *Registered Nurse*.

^dBased on the mean wages for 29–1069 *Physicians and Surgeons, All other*.

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) 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 upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Sharon B. Arnold,
Deputy Director.

[FR Doc. 2017–15886 Filed 7–27–17; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10506]

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 August 28, 2017.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, *Fax Number:* (202) 395–5806 *OR, Email:* OIRA_submission@omb.eop.gov.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at Web site address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: 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. No comments were received in response to the 60-day comment period. 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:* Extension of a currently approved collection; *Title of Information Collection:* Conditions of Participation for Community Mental Health Centers and Supporting Regulations; *Use:* On June 17, 2011, we proposed for the first time new conditions of participation (CoPs) for community mental health centers (CMHCs). We finalized it in the final rule that published October 29, 2013 (78 FR 64604), with an effective date 12 months after publication of the final rule. These CoPs which are based on criteria prescribed in law and are

standards designed to ensure that each facility has properly trained staff to provide the appropriate safe physical environment for patients. These particular standards reflect comparable standards developed by industry organizations such as the Joint Commission. The primary users of this information will be State agency surveyors, CMS and CMHCs for the purpose of ensuring compliance with Medicare CoPs as well as ensuring the quality of care provided by CMHCs to patients. *Form Number:* CMS-10506 (OMB Control number: 0938-1245); *Frequency:* Occasionally; *Affected Public:* Private sector—Business or other for-profits and Not-for-profit organizations; *Number of Respondents:* 68; *Total Annual Responses:* 18,586; *Total Annual Hours:* 2,091. (For policy questions regarding this collection contact Mary Rossi-Coajou at 410-786-6051.)

Dated: July 25, 2017.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2017-15951 Filed 7-27-17; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Culture of Continuous Learning Project: A Breakthrough Series Collaborative for Improving Child Care and Head Start Quality.

OMB No.: New Collection.

Description: The Office of Planning, Research and Evaluation (OPRE) in the Administration for Children and Families (ACF) is proposing an information collection activity for the Culture of Continuous Learning Project. The goal of the project is to assess the feasibility of implementing continuous quality improvement methods in early care and education programs to support the use and sustainability of evidence-based practices. A Breakthrough Series Collaborative (BSC), a specific model designed to support learning and improvement among practitioners at all levels of an organization, will be implemented in Head Start and child care settings. The BSC methodology has not been tested rigorously in early care

and education programs, but has been studied in health care and other fields. The findings will be of broad interest to child care early education programs as well as training and technical assistance providers and researchers, all of whom are interested in improving the quality of services young children receive.

Head Start and child care programs that voluntarily participate in the BSC will be asked to complete a number of implementation tools as part of the BSC activities. Data collection for the feasibility study will involve focus groups, online surveys, direct observation, and document review.

Respondents: Up to 18 early childhood centers will be invited to express interest in participating in the BSC. Up to 8 centers will be selected to participate in the BSC and feasibility study. Core BSC Teams consisting of up to 6 individuals (e.g., directors, lead teachers, assistant teachers, teacher aides, parents, curriculum specialists, etc.) each from four Early Head Start or Head Start programs and four child care programs in a selected geographic location (for a total of 48 individuals); and up to 24 additional teachers or program staff at the same centers who are not part of the Core BSC Team.

ANNUAL BURDEN ESTIMATES

Instrument	Total/annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Selection Questionnaire	18	1	1	18
Pre-Work Assignment: Team Meeting	48	1	1	48
Pre-Work Assignment: Data Collection Plan	16	1	2	32
Plan, Do, Study, Act Worksheets	48	48	.25	576
Discussion Forum Postings	48	48	.25	576
Learning Session Day 1 Evaluation	48	4	.17	33
Learning Session Day 2 Evaluation	48	4	.25	48
Teaching Pyramid Observation Tool (TPOT)	28	2	.25	14
Early Childhood Work Environment Survey (ECWES)	72	2	.25	36
Pre-/Post-Online Survey	72	2	.67	96
Self-report of BSC Activities	72	1	.08	6
Teacher Background Questionnaire	40	2	.17	14
Core BSC Team Focus Group Topic Guide	48	1	1.25	60

Estimated Total Annual Burden Hours: 1,557.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, 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: OPRE

Reports Clearance Officer. Email address: OPREinfocollection@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 Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2017-15850 Filed 7-27-17; 8:45 am]

BILLING CODE 4184-23-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-2562]

Drug Products That Present Demonstrable Difficulties for Compounding Under the Federal Food, Drug, and Cosmetic Act; Establishment of a Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of public docket.

SUMMARY: The Food and Drug Administration (FDA or Agency) is developing a list of drug products and categories of drug products that present demonstrable difficulties for compounding (the Difficult to Compound List). The Agency previously solicited nominations for this list and received approximately 71 unique nominations. FDA is establishing a new public docket so that interested parties can nominate drug products or categories of drug products that were not previously nominated for inclusion on the Difficult to Compound List, resubmit previous nominations with additional supporting information, or submit comments.

DATES: Nominations for the Difficult to Compound List and comments may be submitted to this docket at any time.

ADDRESSES: You may submit nominations or comments as follows:

Electronic Submissions

Submit electronic nominations or comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting nominations or comments. Nominations or comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your nomination or comment will be made public, you are solely responsible for ensuring that your nomination or 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 nomination or comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a nomination or comment with confidential information that you do not wish to be made available to the public, submit the nomination or 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):** Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper nominations or comments submitted to the Division of Dockets Management, FDA will post your nomination or 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. [Docket No. FDA-2017-N-2562] for "Drug Products That Present Demonstrable Difficulties for Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act; Establishment of a Public Docket." Received nominations and 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a nomination or comment with confidential information that you do not wish to be made publicly available, submit your nomination or 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 nominations or 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 Division of Dockets Management. 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 nomination or 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 nominations and 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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Pawanpriti Singh, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5206, Silver Spring, MD 20993-0002, 240-402-8866.

SUPPLEMENTARY INFORMATION:

I. Background

Section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353a) describes the conditions under which a human drug product compounded for an identified individual patient based on a prescription qualifies for exemption from three sections of the FD&C Act: (1) Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice for drugs); (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and (3) section 505 (21 U.S.C. 355) (concerning the approval of human drug products under new drug applications or abbreviated new drug applications). One of the conditions for these exemptions is that the compounded drug product is not "a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product" (section 503A(b)(3)(A) of the FD&C Act). Section 503A(c)(1) of the FD&C Act requires that, before issuing regulations to implement section 503A(b)(3)(A) of the FD&C Act, an advisory committee on compounding be convened and consulted "unless the Secretary determines that the issuance of such

regulations before consultation is necessary to protect the public health.”

Section 503B of the FD&C Act (21 U.S.C. 353b) describes the conditions that must be met for human drugs compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility to qualify for exemptions from three sections of the FD&C Act: (1) Section 502(f)(1) (21 U.S.C. 352(f)(1)); (2) section 505 (21 U.S.C. 355); and section 582 (21 U.S.C. 360eee–1) (concerning drug supply chain security requirements). Section 503B does not provide an exemption from section 501(a)(2)(B).

One of the conditions in section 503B that must be satisfied for a compounded drug to qualify for the exemptions in that section is that the drug either (1) is not identified (directly or as part of a category of drugs) on a list published by the Secretary, of drugs or categories of drugs that present demonstrable difficulties for compounding that are reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug or category of drugs, taking into account the risks and benefits to patients, or (2) is compounded in accordance with all applicable conditions identified on the list as conditions that are necessary to prevent the drug or category of drugs from presenting such demonstrable difficulties (see section 503B(a)(6)(A) and (a)(6)(B) of the FD&C Act). Section 503B(c)(2) of the FD&C Act requires that before issuing regulations to implement section 503B(a)(6) of the FD&C Act, an advisory committee on compounding be convened and consulted.

At a meeting on July 13 and 14, 2000, an advisory committee on compounding (specifically, the Pharmacy Compounding Advisory Committee (PCAC)) discussed and provided FDA with advice about the Agency's efforts to develop a list of drugs that present demonstrable difficulties for compounding under section 503A of the FD&C Act. FDA published a notice of that meeting in the **Federal Register** on June 29, 2000 (65 FR 40104). In the **Federal Register** of December 4, 2013 (78 FR 72840), FDA invited all interested persons to nominate drug products or categories of drug products for inclusion on the Difficult to Compound List. Nominators were asked to include the name of the drug product or category of drug products being nominated, as well as the reason the drug product or category of drug products should be included on the list, taking into account the risks and benefits to patients. The notice also included a list of factors that may be relevant to determining whether or not

a drug product or category of drug products should or should not be included on the Difficult to Compound List. Approximately 71 unique drug products or categories of drug products were nominated for this list.

On June 18, 2015, the PCAC reviewed and discussed FDA's proposed criteria for evaluating whether drug products or categories of drug products are demonstrably difficult to compound under sections 503A and 503B of the FD&C Act. After considering the PCAC's discussion, FDA refined the criteria and presented the changes to the PCAC on March 9, 2016. The six criteria presented to the PCAC for evaluating whether a drug product or category of drug products is demonstrably difficult to compound are the following: (1) The complexity of the formulation; (2) the complexity of the drug delivery mechanism; (3) the complexity of the dosage form; (4) the complexity of achieving bioavailability; (5) the complexity of the compounding process; and (6) the complexity of physicochemical or analytical testing. Additional information regarding these criteria can be found in the briefing package for the March 2016 PCAC meeting. See <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompounding/AdvisoryCommittee/UCM486146.pdf>.

II. Establishment of a Public Docket

FDA is establishing a public docket so that interested parties can nominate drug products or categories of drug products for inclusion on the Difficult to Compound List, resubmit previous nominations with additional supporting information, or submit comments.

Nominations should include the following two items for each drug product or category of drug products nominated, and any other relevant additional information available:

- The name of the drug product or drug product category;
- The reason the drug product or drug product category should be included on the list, taking into account any risks and benefits to patients.

To facilitate FDA's review, nominations may include responses to the following six questions, which are related to the criteria FDA presented to the PCAC for evaluating whether drug products and categories of drug products are difficult to compound under sections 503A and 503B of the FD&C Act:

1. Does the drug product or category of drug products have a complex formulation that presents a demonstrable difficulty for

compounding that is reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug product?

2. Does the drug product or category of drug products have a complex drug delivery mechanism that presents a demonstrable difficulty for compounding that is reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug product?

3. Does the drug product or category of drug products involve a complex dosage form that presents a demonstrable difficulty for compounding that is reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug product?

4. Does the drug product or category of drug products involve complexities in achieving and/or assessing bioavailability that present a demonstrable difficulty for compounding that is reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug product?

5. Does compounding the drug product or category of drug products involve a complex compounding process that presents a demonstrable difficulty for compounding that is reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug product?

6. Does compounding the drug product or category of drug products necessitate complex physicochemical or analytical testing that presents a demonstrable difficulty for compounding that is reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug product?

It is not necessary for a previously nominated drug product or category of drug products to be renominated to this docket. Previously nominated drug products or categories of drug products may be renominated to this docket if the nominator wants to provide additional supporting information, *e.g.*, information specific to the six questions listed above related to FDA's proposed evaluation criteria. Interested parties can also submit comments on nominated drug products or categories of drug products, or on this document, via this docket.

Previous nominations to the Difficult to Compound List or comments submitted in response to the December 4, 2013 **Federal Register** notice can be viewed on <https://www.regulations.gov> under docket number FDA–2013–N–1523, or by going to the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 24, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017-15900 Filed 7-27-17; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-4301]

Fostering Medical Innovation: A Plan for Digital Health Devices; Software Precertification Pilot Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA, the Agency, or we) Center for Devices and Radiological Health (CDRH or Center) is announcing its Software Precertification Pilot Program. The program aims to evaluate a new approach toward software products, including a precertification program for the assessment of companies that perform high-quality software design and testing. This voluntary pilot program is part of FDA's ongoing efforts to develop pragmatic approaches to balance benefits and risks of digital health products. FDA intends to develop a precertification program that could replace the need for a premarket submission in some cases and allow for decreased submission content and/or faster review of marketing applications for software products in other cases. During the pilot program, FDA customers, including pilot participants, will have the opportunity to provide input on the development of the precertification program.

DATES: FDA is seeking participation in the voluntary Software Precertification pilot program beginning August 1, 2017. See the "Participation" section for instructions on how to submit a request to participate. The voluntary Software Precertification pilot program will select up to nine participants who best match the selection criteria. This pilot program will begin September 1, 2017.

ADDRESSES: You may submit comments 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-2017-N-4301 for "Fostering Medical Innovation: A Plan for Digital Health Devices; Software Precertification Pilot Program." 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.

FOR FURTHER INFORMATION CONTACT:

Bakul Patel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5458, Silver Spring, MD 20993, 301-796-5528, Bakul.Patel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA recognizes that an efficient, risk-based approach to regulating digital health technology will foster innovation of digital health products. FDA's traditional approach to moderate and higher risk hardware-based medical devices is not well suited for the faster iterative design, development, and type of validation used for software products. An agile paradigm is necessary to accommodate the faster rate of development and innovation of software devices as compared to other types of devices. Traditional implementation of the premarket requirements may impede or delay patient access to critical evolutions of software technology, particularly those presenting a lower risk to patients. To evaluate a new approach toward software, FDA is launching a pilot of a precertification program for the assessment of companies that perform high-quality software design and testing. The Software Precertification (Pre-Cert) pilot program is part of FDA's ongoing efforts

to develop pragmatic approaches within its existing authorities to optimally foster the development of high-quality, safe and effective digital health products while assuring timely patient access. FDA has previously discussed the idea of a precertification program in various forums and invites further input from all stakeholders throughout this pilot. FDA intends to establish a process for company precertification that could replace the need for a premarket submission for certain products or allow for decreased submission content and/or faster review of marketing submissions for other products. CDRH plans to select its first participants and initiate the voluntary Software Pre-Cert pilot program focusing on receiving input on the activities and criteria critical to streamlining premarket review of software products by September 1, 2017.

FDA is issuing its Digital Health Innovation Action Plan.¹ The Action Plan presents FDA's vision for the regulation of digital health technologies that are medical devices and the actions FDA intends to pursue to provide greater clarity regarding what types of digital health technology are subject to regulation. In the Action Plan, FDA describes a forward-leaning approach to ensure that we will implement the right policies and regulatory tools. The Software Pre-Cert pilot program is one component of FDA's comprehensive approach to digital health medical devices described in the Action Plan. FDA welcomes comments on the policies, pathways, and regulatory tools the Agency should consider in designing a new paradigm for overseeing digital health medical devices. (See information on how to submit comments to the public docket in the **ADDRESSES** section.)

The Software Pre-Cert pilot will help inform the development of the Pre-Cert program for software developers, including what criteria can be used to assess whether a company consistently and reliably engages in high-quality software design and testing (validation) and ongoing maintenance of its software products. FDA and companies participating in the pilot program will explore the use of external software development standards to reduce premarket software documentation burden. Precertified companies that have demonstrated a culture of quality and organizational excellence could bring certain types of digital health products to market without FDA premarket review or after a streamlined, less-burdensome FDA premarket

review. The criteria developed and evaluated for precertification during the pilot program may also be used to inform the establishment of a third-party certification program, in which third parties may facilitate the precertification of companies, and will enable greater patient access to digital health technologies and will allow the Agency to devote more resources to the evaluation of higher risk technologies/products.

Companies are eligible to participate in this voluntary Software Pre-Cert pilot program based on the criteria listed in Section A. Participation. FDA will select up to nine participants, who best match the selection criteria and who reflect the broad spectrum of software developers (e.g., both small and large software development firms). FDA intends to include companies that develop a range of products (both low and high risk) to learn how to apply the Software Pre-Cert program to different product types. FDA also intends to include companies that are not considered to be traditional medical device manufacturers, but who intend to make digital health technology.

The purpose of the Software Pre-Cert pilot is to leverage customer input to develop a program that can help reduce the time and cost of market entry for software developers that FDA determines reliably manufacture high-quality, safe and effective digital health devices. This voluntary pilot program does not represent a new requirement; instead, it is an opportunity to help FDA develop an innovative approach for digital health technology.

A. Participation

Companies that may be eligible to participate in this voluntary Software Pre-Cert pilot program are limited to those firms who follow the procedures set out in Section B and also meet the following selection qualities that follow.

1. The company must be developing or planning to develop a software product that meets the definition of a device in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)).

2. The company has an existing track record in developing, testing, and maintaining software products demonstrating a culture of quality and organizational excellence measured and tracked by Key Performance Indicators (KPIs) or other similar measures.

3. While participating in the pilot, the company must agree to:

- a. Provide access to measures described in selection quality number 2, listed previously (KPIs or similar measures).

- b. Collect real-world postmarket performance data and provide it to FDA.

- c. Be available for real-time consultations with FDA.

- d. Be available for site visits from FDA officials.

- e. Provide information about the firm's quality management system.

B. Procedures

To be considered for the voluntary Software Pre-Cert pilot program, a company should submit a statement of interest for participation to FDAPre-CertPilot@fda.hhs.gov. The statement of interest should include agreement to the selection qualities listed in Section A. Participation.

The following captures the proposed process for the voluntary Software Pre-Cert pilot program:

1. FDA will collect statements of interest for participation in the pilot program beginning August 1, 2017.

2. FDA will evaluate the statements of interest for participation and select no more than nine participants, who best meet the selection criteria and who reflect the broad spectrum of software developers, including companies that develop a range of products (both low and high risk). FDA will work with the selected participants to develop criteria for precertification and the types of information that should be reviewed during the precertification process or postmarket, rather than during the review of a premarket submission.

- a. Depending on the stage of development of the company's software product, FDA will work interactively with the participating company through the Q-submission process, including via Pre-Submissions, Informational Meetings, Submission Issue Meetings, etc. (Ref. 1).

3. Enrollment in the pilot program will be ongoing throughout the duration of the program. FDA will apply lessons learned from the initial participants in the pilot program to refine the precertification program in collaboration with participants.

During this voluntary Software Pre-Cert pilot program, CDRH staff intends to be available to answer questions or concerns that may arise. The voluntary Software Pre-Cert pilot program participants will be asked to comment on and discuss their experiences with the Software Pre-Cert pilot process.

II. Beginning Date of the Software Pre-Cert Pilot Program

FDA intends to accept requests for participation in the voluntary Software Pre-Cert pilot program beginning August 1, 2017. This pilot program will begin September 1, 2017.

¹ Available at <https://www.fda.gov/MedicalDevices/DigitalHealth/UCM567265>.

III. Paperwork Reduction Act of 1995

This notice refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subparts A through E have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; and the collections of information in “Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff” have been approved under OMB control number 0910–0756.

IV. Reference

The following reference is on display in the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at <https://www.regulations.gov>. FDA has verified the Web site address, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. “Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff; Guidance for Industry and Food and Drug Administration Staff,” February 2014, available at <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm311176.pdf>.

Dated: July 24, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–15891 Filed 7–27–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Division of Behavioral Health, Office of Clinical and Preventive Services; Funding Opportunities: Domestic Violence Prevention Initiative

Announcement Type: New.

Funding Announcement Number:
HHS–2017–IHS–DVPI–0001.

Catalog of Federal Domestic Assistance Number (CFDA): 93.933.

Key Dates

Application Deadline Date: August 31, 2017.

Review Date: September 11, 2017.

Earliest Anticipated Start Date:
September 30, 2017.

Signed Tribal Resolutions Due Date:
August 31, 2017.

Proof of Non-Profit Status Due Date:
August 31, 2017.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS), Office of Clinical and Preventive Services (OCPS), Division of Behavioral Health (DBH) is accepting applications for a three-year funding cycle, to continue the planning, development, and implementation of the Domestic Violence Prevention Initiative (DVPI). This program was first established by the Omnibus Appropriations Act of 2009, Public Law 111–8, 123 Stat. 524, 735, and continued in the annual appropriations acts since that time. This program is authorized under the authority of 25 U.S.C. 13, the Snyder Act, and the Indian Health Care Improvement Act, 25 U.S.C. 1601–1683. This program is described in the Catalog of Federal Domestic Assistance under 93.933.

Background

The DBH serves as the primary source of national advocacy, policy development, management and administration of behavioral health, alcohol and substance abuse, and family violence prevention programs. In 2015, DBH funded 57 Tribes, Tribal organizations, Urban Indian Organization (UIOs), and IHS federal facilities that participate in a nationally coordinated project to expand outreach and increase awareness of domestic and sexual violence and provide victim advocacy, intervention, case coordination, policy development, community response teams, and community and school education programs. The DVPI promotes the development of evidence-based and practice-based models that represent culturally appropriate prevention and treatment approaches to domestic and sexual violence from a community-driven context.

Purpose

The primary purpose of this grant program is to accomplish the DVPI goals listed below:

1. Build Tribal, UIO, and Federal capacity to provide coordinated

community responses to American Indian/Alaska Native (AI/AN) victims of domestic and sexual violence.

2. Increase access to domestic and sexual violence prevention, advocacy, crisis intervention, and behavioral health services for AI/AN victims and their families.

3. Promote trauma-informed services for AI/AN victims of domestic and sexual violence and their families.

4. Offer health care provider and community education on domestic and sexual violence.

5. Respond to the health care needs of AI/AN victims of domestic and sexual violence.

6. Incorporate culturally appropriate practices and/or faith-based services for AI/AN victims of domestic and sexual violence.

To accomplish the DVPI goals, IHS invites applicants to address one of the Purpose Areas below:

- *Purpose Area 1:* Domestic and Sexual Violence Prevention, Advocacy, and Coordinated Community Responses
- *Purpose Area 2:* Provide Forensic Health Care Services

Evidence-Based Practices, Practice-Based Evidence, Promising Practices, and Local Efforts

IHS strongly emphasizes the use of data and evidence in policymaking and program development and implementation. Applicants under each Purpose Area must identify one or more evidence-based practice, practice-based evidence, best or promising practice, and/or local effort they plan to implement in the Project Narrative section of their application. The DVPI program Web site (<https://www.ihs.gov/dvpi/bestpractices/>) is one resource that applicants may use to find information to build on the foundation of prior domestic and sexual violence prevention and treatment efforts, in order to support the IHS, Tribes, Tribal organizations, and UIOs in developing and implementing Tribal and/or culturally appropriate domestic and sexual violence prevention and early intervention strategies.

Purpose Areas

Purpose Area 1: Domestic and Sexual Violence Prevention, Advocacy, and Coordinated Community Responses.

IHS is seeking applicants to address the following broad objectives:

- Expand crisis intervention, counseling, advocacy, behavioral health, and case management services to victims of domestic and sexual violence;
- Foster coalitions and networks to improve coordination and collaboration

among victim service providers, health care providers, and other responders;

- Educate and train service providers on trauma, domestic violence, and sexual assault and its impact on victims;
- Promote community education for adults and youth on domestic and sexual violence;
- Improve organizational practices to improve services for individuals seeking services for domestic and sexual violence;
- Establish coordinated community response policies, protocols, and procedures to enhance domestic and sexual violence intervention and prevention;
- Integrate culturally appropriate practices and/or faith-based services to facilitate the social and emotional well-being of victims and their children; and
- Implement trauma informed care interventions to support victims and their children.

Purpose Area 2: Forensic Health Care Services. IHS is seeking applicants to address the following broad objectives:

- Expand available medical forensic services to victims of domestic and sexual violence;
- Foster coalitions and networks to improve coordination and collaboration among forensic health care programs to ensure adequate services exist either on-site or by referral for victims of domestic and sexual violence 24/7 year round;
- Educate and train providers to conduct medical forensic examinations;
- Promote community education on available medical forensic services;
- Improve health system organizational practices to improve medical forensic services and care coordination among victim services;
- Establish local health system policies for sexual assault, domestic violence, and child maltreatment;
- Integrate culturally appropriate treatment services throughout the medical forensic examination process; and
- Implement trauma informed care interventions to support victims and their children.

II. Award Information

Type of Award

Grant.

Estimated Funds Available

The total amount of funding identified for the current fiscal year (FY) 2017 is approximately \$3,600,000. Individual award amounts are anticipated to be from \$50,000 to \$200,000. IHS expects to allocate funding for the 12 IHS service areas as described below. Applicants will be

awarded according to their location within their respective IHS service area and will not compete with applicants from other IHS service areas. UIOs applicants will be selected from a category set aside for UIO applicants only. UIO awards will be \$100,000 each. The amount of funding available for competing and continuation awards issued under this announcement are subject to the availability of appropriations and budgetary priorities of the Agency. IHS is under no obligation to make awards that are selected for funding under this announcement.

Anticipated Number of Awards

The amounts made available for the DVPI shall be allocated at the discretion of the Director, IHS and shall remain available until expended. IHS utilizes a national funding formula developed in consultation with Tribes and the National Tribal Advisory Committee (NTAC) on behavioral health, as well as conferring with UIOs. The funding formula provides the allocation methodology for each IHS Service Area.

The number of anticipated awards is dependent on the number of applications received in response to the announcement and available funds. If funds remain after all applications are awarded in each IHS service area, the leftover amount will be compiled and will be used to award applications according to rank order without regard to IHS service area until all funds are awarded. The funding breakdown by area is as follows:

Alaska IHS Service Area

IHS expects to provide \$420,000 in total awards for a 12-month project period.

Albuquerque IHS Service Area

IHS expects to provide \$191,000 in total awards for a 12-month project period.

Bemidji IHS Service Area

IHS expects to provide \$204,000 in total awards for a 12-month project period.

Billings IHS Service Area

IHS expects to provide \$184,000 in total awards for a 12-month project period.

California IHS Service Area

IHS expects to provide one award for a total of \$144,000 for a 12-month project period.

Great Plains IHS Service Area

IHS expects to provide \$330,000 in total awards for a 12-month project period.

Nashville IHS Service Area

IHS expects to provide one award for a total of \$80,000 for a 12-month project period.

Navajo IHS Service Area

IHS expects to provide \$534,000 in total awards for a 12-month project period.

Oklahoma City IHS Service Area

IHS expects to provide \$520,000 in total awards for a 12-month project period.

Phoenix IHS Service Area

IHS expects to provide \$330,000 in total awards for a 12-month project period.

Portland IHS Service Area

IHS expects to provide \$208,000 in total awards for a 12-month project period.

Tucson IHS Service Area

IHS expects to provide one award for a total of \$55,000 for a 12-month project period.

Urban Indian Organizations

IHS expects to provide \$400,000 in total awards for a 12-month project period.

Project Period

The project period is for three years and will run consecutively from September 30, 2017 to September 29, 2020.

III. Eligibility Information

I.

1. Eligibility

To be eligible for this FY2017 funding opportunity announcement, only “New Applicants” are eligible to apply. An applicant cannot be an existing DVPI awardee under this announcement. Also, an applicant must be defined as one of the following under 25 U.S.C. 1603:

- A Federally-recognized Indian Tribe as defined by 25 U.S.C. 1603(14). The term “Indian Tribe” means any Indian Tribe, band, nation, or other organized group or community, including any Alaska Native village or group or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (85 Stat. 688) [43 U.S.C. 1601 *et seq.*], which is recognized as eligible for the

special programs and services provided by the United States to Indians because of their status as Indians.

- A Tribal organization as defined by 25 U.S.C. 1603(26). The term “organization” has the meaning given the term in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304): “Tribal organization” means the recognized governing body of any Indian tribe; any legally established organization of Indians which is controlled, sanctioned, or chartered by such governing body or which is democratically elected by the adult members of the Indian community to be served by such organization and which includes the maximum participation of Indians in all phases of its activities: Provided, That in any case where a contract is let or grant made to an organization to perform services benefiting more than one Indian Tribe, the approval of each such Indian tribe shall be a prerequisite to the letting or making of such contract or grant.

- An Urban Indian organization as defined by 25 U.S.C. 1603(29): A nonprofit corporate body situated in an urban center, governed by an Urban Indian controlled board of directors, and providing for the maximum participation of all interested Indian groups and individuals, which body is capable of legally cooperating with other public and private entities for the purpose of performing the activities described in 25 U.S.C. 1653(a). Applicants must provide proof of non-profit status with the application, *e.g.*, 501(c)(3).

Note: Please refer to Section IV.2 (Application and Submission Information/Subsection 2, Content and Form of Application Submission) for additional proof of applicant status documents required, such as Tribal resolutions, proof of non-profit status, etc.

2. Cost Sharing or Matching

The IHS does not require matching funds or cost sharing for grants or cooperative agreements.

3. Other Requirements

If application budgets exceed the highest dollar amount outlined under the “Estimated Funds Available” section within this funding announcement, the application will be considered ineligible and will not be reviewed for further consideration. If deemed ineligible, IHS will not return the application. The applicant will be notified by email by the Division of Grants Management (DGM) of this decision.

Tribal Resolution

An Indian Tribe or Tribal organization that is proposing a project affecting another Indian Tribe must include resolutions from all affected Tribes to be served. Applications by Tribal organizations will not require a specific Tribal resolution if the current Tribal resolution(s) under which they operate would encompass the proposed grant activities.

An official signed Tribal resolution must be received by the DGM prior to a Notice of Award (NoA) being issued to any applicant selected for funding. However, if an official signed Tribal resolution cannot be submitted with the electronic application submission prior to the official application deadline date, a draft Tribal resolution must be submitted by the deadline in order for the application to be considered complete and eligible for review. The draft Tribal resolution is not in lieu of the required signed resolution, but is acceptable until a signed resolution is received. If an official signed Tribal resolution is not received by DGM when funding decisions are made, then a NoA will not be issued to that applicant and they will not receive any IHS funds until such time as they have submitted a signed resolution to the Grants Management Specialist listed in this Funding Announcement.

Proof of Non-Profit Status

Organizations claiming non-profit status must submit proof. A copy of the 501(c)(3) Certificate must be received with the application submission by the application deadline date listed under the Key Dates section on page one of this announcement.

An applicant submitting any of the above additional documentation after the initial application submission due date is required to ensure the information was received by IHS DGM by obtaining documentation confirming delivery (*i.e.* FedEx tracking, postal return receipt, etc.).

IV. Application and Submission Information

1. Obtaining Application Materials

The application package and detailed instructions for this announcement can be found at <http://www.Grants.gov> or <https://www.ihs.gov/dgm/funding/>.

Questions regarding the electronic application process may be directed to Mr. Paul Gettys at (301) 443–2114 or (301) 443–5204.

2. Content and Form Application Submission

The applicant must include the project narrative as an attachment to the application package. Mandatory documents for all applicants include:

- Table of contents.
 - Abstract (one page) summarizing the project.
 - Application forms:
 - SF–424, Application for Federal Assistance.
 - SF–424A, Budget Information—Non-Construction Programs.
 - SF–424B, Assurances—Non-Construction Programs.
 - Statement of Need (must be single-spaced and not exceed two pages).
 - Includes the Tribe, Tribal organization, or UIO background information.
 - Project Narrative (must be included as an attachment to the application package and must be single-spaced and not exceed 10 pages).
 - Includes proposed scope of work, required objectives, and activities that provide a description of what will be accomplished, including a one-page timeline chart, and a local data collection plan.
 - Budget Justification and Narrative (must be single-spaced and not exceed four pages).
 - Tribal Resolution(s).
 - Letter(s) of Support:
 - *For all applicants:* Local organizational partners;
 - *For all applicants:* Community partners;
 - *For Tribal organizations:* From the board of directors (or relevant equivalent);
 - *For Urban Indian organizations:* From the board of directors (or relevant equivalent).
 - 501(c)(3) Certificate (if applicable).
 - Biographical sketches for all Key Personnel (*e.g.*, project director, project coordinator, grants coordinator, etc.).
 - Contractor/Consultant resumes or qualifications and scope of work.
 - Disclosure of Lobbying Activities (SF–LLL).
 - Certification Regarding Lobbying (GG–Lobbying Form).
 - Copy of current Negotiated Indirect Cost rate (IDC) agreement (required in order to receive IDC).
 - Organizational Chart (optional).
 - Documentation of current Office of Management and Budget (OMB) Financial Audit (if applicable).
- Acceptable forms of documentation include:
- Email confirmation from Federal Audit Clearinghouse (FAC) that audits were submitted; or

○ Face sheets from audit reports. These can be found on the FAC Web site: <https://harvester.census.gov/facdissem/Main.aspx>.

Public Policy Requirements

All Federal-wide public policies apply to IHS grants and cooperative agreements with exception of the Discrimination policy.

Requirements for Statement of Need

The statement of need describes the history and current situation in the applicant's Tribal community ("community" means the applicant's Tribe, village, Tribal organization, or consortium of Tribes or Tribal organizations). The statement of need provides the facts and evidence that support the need for the project and establishes that the Tribe, Tribal organization, or UIO understands the problems and can reasonably address them and provides background information on the Tribe, Tribal organization, or UIO. The statement of need must not exceed two single-spaced pages and must be type written, have consecutively number pages, use black type not smaller than 12 point, and printed on one side of standard size 8½" x 11" paper.

Requirements for Project and Budget Narratives

A. Project Narrative 10 Pages

The project narrative (Parts A through E listed below) should be a separate Word document that not to exceed 10 pages and must: Be single-spaced, type written, have consecutively numbered pages, use black type not smaller than 12 points, and be printed on one side only of standard size 8½" x 11" paper.

Be sure to succinctly address and answer all questions listed under the evaluation criteria (refer to Section V.1, Evaluation Criteria in this announcement) and place all responses and required information in the correct section (noted below), or they will not be considered or scored. These narratives will assist the Objective Review Committee (ORC) in becoming familiar with the applicant's activities and accomplishments prior to this possible grant award. If the narrative exceeds the page limit, only the first 10 pages will be reviewed. The 10-page limit for the narrative does not include the table of contents, abstract, statement of need, standard forms, Tribal resolution(s), budget, budget justification narrative, and/or other appendix items.

There are five (5) parts to the project narrative:

- Part A—Goals and Objectives;

- Part B—Project Activities;
- Part C—Timeline Chart (template provided);
- Part D—Organizational Capacity and Staffing/Administration; and
- Part E—Local Data Collection Plan.

Below are additional details about what must be included in the project narrative.

Part A: Goals and Objectives

- Describe the purpose of the proposed project that includes a clear statement of goals.
- Specifically address all eight (8) required objectives listed for DVPI Purpose Area #1 or Purpose Area #2. The objectives should be clearly outlined in the project narrative. If the application does not address all required objectives, the application will be considered ineligible and will not be reviewed for further consideration.
- Applicants are allowed to include additional objectives if there are proposed activities that do not fall within the required objectives. Additional activities not related to the required objectives must clearly correspond to a specific objective.

Part B: Project Activities

- Clearly outline how the identified project activities are linked to the objectives listed for DVPI Purpose Area #1 or Purpose Area #2.
- Describe how project activities will increase the capacity of the identified community to plan and improve the coordination of a collaborative domestic and sexual violence services.
- Describe anticipated barriers to progress of the project and how the barriers will be addressed.
- If the applicant plans to include an advisory body in the project, describe its membership, roles and functions, and frequency of meetings.
- Identify any other organization(s) that will participate in the proposed project. Describe their roles, responsibilities, and demonstrate their commitment to the project. Include a list of these organizations as an attachment to the application. In the attached list, indicate the organizations that the Tribe, Tribal organization, or UIO has worked with or currently works with. [Note: The attachment will not count as part of the 10-page maximum.]

Part C: Timeline

- Provide a one-year (first budget year) timeline chart depicting a realistic timeline for the project period showing key activities, milestones, and responsible staff. These key activities should include the requirements outlined for DVPI Purpose Area #1 or

Purpose Area #2. [Note: The timeline chart should be included as part of the Project Narrative as specified here. It should not be placed as an attachment.] The timeline chart should not exceed one page.

Part D: Organizational Capacity and Staffing/Administration

- Describe the management capability and experience of the applicant Tribe, Tribal organization, or UIO and other participating organizations in administering similar grants and projects.
- Discuss the applicant Tribe, Tribal organization, UIO experience and capacity to provide culturally appropriate/competent services to the community and specific populations of focus.
- Describe the resources available for the proposed project (e.g., facilities, equipment, information technology systems, and financial management systems).
- Describe how project continuity will be maintained if/when there is a change in the operational environment (e.g., staff turnover, change in project leadership, change in elected officials) to ensure project stability over the life of the grant.
- Provide a complete list of staff positions for the project, including the project director, project coordinator, and other key personnel, showing the role of each and their level of effort and qualifications.

• Include position descriptions as *attachments* to the project proposal/application for the project director, project coordinator, and all key personnel. Position descriptions should not exceed one page each. [Note: Attachments will not count against the 10 page maximum.]

• For individuals that are identified and currently on staff, include a biographical sketch for the project director, project coordinator, and other key positions as attachments to the project proposal/application. Each biographical sketch should not exceed one page. [Note: Attachments will not count against the 10 page maximum.]

Do not include any of the following:

- Personally Identifiable Information;
- Resumes; or
- Curriculum Vitae.

Part E: Local Data Collection Plan

- The Local Data Collection Plan (LDCP) template does not count toward the page limit. [Note: The LDCP should be placed as an attachment.]
- Utilizing the LDCP template, applicants should describe a plan for gathering data relevant to the DVPI

Purpose Area objectives to which you are applying. This includes a plan for each activity that details:

- A data collection method, a data source, a data measurement tool, identified staff for data management, and a data collection timeline.
- In addition, a narrative section after the template should describe how the applicant will submit the required data, how the applicant will monitor the data, and outline the applicant's ability to ensure accurate data tracking and reporting (e.g., submission of annual progress reporting requirements that will be collected annually through the project period on the web-based DVPI data portal).
- How the project will work with the regional Technical Assistance (TA) Providers for evaluation (the regional Tribal Epidemiology Center). The TA Providers for evaluation are available to each grantee to help with refining the LDCP, technical assistance with evaluation plans, data collection, data measurement, and data management to the grantees.

B. Budget Narrative 4 Pages

This narrative must include a line item budget with a narrative justification for all expenditures identifying reasonable allowable, allocable costs necessary to accomplish the goals and objectives as outlined in the project narrative. Budget should match the scope of work described in the project narrative. The budget and budget narrative should not exceed *four* pages.

Templates

Templates are provided for the project narrative, timeline chart, LDCP, budget and budget narrative, and biographical sketch for use by the applicant. These templates can be located and downloaded at the DVPI Web site at: <https://www.ihs.gov/dvpi/newsannouncements>.

3. Submission Dates and Times

Applications must be submitted electronically through *Grants.gov* by 11:59 p.m. Eastern Daylight Time (EDT) on the Application Deadline Date listed in the Key Dates section on page one of this announcement. Any application received after the application deadline will not be accepted for processing, nor will it be given further consideration for funding. *Grants.gov* will notify the applicant via email if the application is rejected.

If technical challenges arise and assistance is required with the electronic application process, contact *Grants.gov* Customer Support via email

to support@grants.gov or at (800) 518-4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays). If problems persist, contact Mr. Gettys (Paul.Gettys@ihs.gov), DGM Grant Systems Coordinator, by telephone at (301) 443-2114 or (301) 443-5204. Please be sure to contact Mr. Gettys at least ten days prior to the application deadline. Please do not contact the DGM until you have received a *Grants.gov* tracking number. In the event you are not able to obtain a tracking number, call the DGM as soon as possible.

4. Intergovernmental Review

Executive Order 12372 requiring intergovernmental review is not applicable to this program.

5. Funding Restrictions

- Pre-award costs are not allowable.
- The available funds are inclusive of direct and appropriate indirect costs.
- Only one grant/cooperative agreement will be awarded per applicant.
- IHS will not acknowledge receipt of applications.

6. Electronic Submission Requirements

All applications must be submitted electronically. Please use the <http://www.Grants.gov> Web site to submit an application electronically and select the "Find Grant Opportunities" link on the homepage. Follow the instructions for submitting an application under the "Package" tab. Electronic copies of the application may not be submitted as attachments to email messages addressed to IHS employees or offices.

If the applicant needs to submit a paper application instead of submitting electronically through *Grants.gov*, a waiver must be requested. Prior approval must be requested and obtained from Mr. Robert Tarwater, Director, DGM, (see Section IV.6 below for additional information). A written waiver request must be sent to GrantsPolicy@ihs.gov with a copy to Robert.Tarwater@ihs.gov. The waiver must (1) be documented in writing (emails are acceptable), before submitting a paper application, and (2) include clear justification for the need to deviate from the required electronic grants submission process.

Once the waiver request has been approved, the applicant will receive a confirmation of approval email containing submission instructions and the mailing address to submit the application. A copy of the written approval must be submitted along with the hardcopy of the application that is mailed to DGM. Paper applications that

are submitted without a copy of the signed waiver from the Director of the DGM will not be reviewed or considered for funding. The applicant will be notified via email of this decision by the Grants Management Officer of the DGM. Paper applications must be received by the DGM no later than 5:00 p.m., EDT, on the Application Deadline Date listed in the Key Dates section on page one of this announcement. Late applications will not be accepted for processing or considered for funding. Applicants that do not adhere to the timelines for System for Award Management (SAM) and/or <http://www.Grants.gov> registration or that fail to request timely assistance with technical issues will not be considered for a waiver to submit a paper application.

Please be aware of the following:

- Please search for the application package in <http://www.Grants.gov> by entering the CFDA number or the Funding Opportunity Number. Both numbers are located in the header of this announcement.
- If you experience technical challenges while submitting your application electronically, please contact *Grants.gov* Support directly at: support@grants.gov or (800) 518-4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays).
- Upon contacting *Grants.gov*, obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver from the agency must be obtained.
- Applicants are strongly encouraged not to wait until the deadline date to begin the application process through *Grants.gov* as the registration process for SAM and *Grants.gov* could take up to fifteen working days.
- Please use the optional attachment feature in *Grants.gov* to attach additional documentation that may be requested by the DGM.
- All applicants must comply with any page limitation requirements described in this funding announcement.
- After electronically submitting the application, the applicant will receive an automatic acknowledgment from *Grants.gov* that contains a *Grants.gov* tracking number. The DGM will download the application from *Grants.gov* and provide necessary copies to the appropriate agency officials. Neither the DGM nor the DBH will notify the applicant that the application has been received.
- Email applications will not be accepted under this announcement.

Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS)

All IHS applicants and grantee organizations are required to obtain a DUNS number and maintain an active registration in the SAM database. The DUNS number is a unique 9-digit identification number provided by D&B which uniquely identifies each entity. The DUNS number is site specific; therefore, each distinct performance site may be assigned a DUNS number. Obtaining a DUNS number is easy, and there is no charge. To obtain a DUNS number, you may access it through <http://fedgov.dnb.com/webform>, or to expedite the process, call (866) 705-5711.

All HHS recipients are required by the Federal Funding Accountability and Transparency Act of 2006, as amended ("Transparency Act"), to report information on sub-awards. Accordingly, all IHS grantees must notify potential first-tier sub-recipients that no entity may receive a first-tier sub-award unless the entity has provided its DUNS number to the prime grantee organization. This requirement ensures the use of a universal identifier to enhance the quality of information available to the public pursuant to the Transparency Act.

System for Award Management (SAM)

Organizations that were not registered with Central Contractor Registration and have not registered with SAM will need to obtain a DUNS number first and then access the SAM online registration through the SAM home page at <https://www.sam.gov> (U.S. organizations will also need to provide an Employer Identification Number from the Internal Revenue Service that may take an additional 2–5 weeks to become active). Completing and submitting the registration takes approximately one hour to complete and SAM registration will take 3–5 business days to process. Registration with the SAM is free of charge. Applicants may register online at <https://www.sam.gov>.

Additional information on implementing the Transparency Act, including the specific requirements for DUNS and SAM, can be found on the IHS Grants Management, Grants Policy Web site: <http://www.ihs.gov/dgm/policytopics/>.

V. Application Review Information

The instructions for preparing the application narrative also constitute the evaluation criteria for reviewing and scoring the application. Weights assigned to each section are noted in parentheses. The 10 page narrative

should include only the first year of activities; information for multi-year projects should be included as an appendix. The narrative section should be written in a manner that is clear to outside reviewers unfamiliar with prior related activities of the applicant. It should be well-organized, succinct, and contain all information necessary for reviewers to understand the project fully. Points will be assigned to each evaluation criteria adding up to a total of 100 points. A minimum score of 65 points is required for funding. Points are assigned as follows:

1. Evaluation Criteria

Applications will be reviewed and scored according to the quality of responses to the required application components in Sections A–E outlined below. In developing the required sections of this application, use the instructions provided for each section, which have been tailored to this program. The application must use the five sections (Sections A–E) listed below in developing the application. The applicant must place the required information in the correct section *or it will not be considered for review*. The application will be scored according to how well the applicant addresses the requirements for each section listed below. The number of points after each section heading is the maximum number of points the review committee may assign to that section. Although scoring weights are not assigned to individual bullets, each bullet is assessed deriving the overall section score.

A. Statement of Need (History and Current Situation in Your Tribal Community) (35 Points)

The statement of need should not exceed two single-spaced pages.

1. Identify the proposed catchment area and provide demographic information on the population(s) to receive services through the targeted systems or agencies, *e.g.*, race, ethnicity, Federally recognized Tribe, language, age, socioeconomic status, sexual identity (sexual orientation, gender identity), and other relevant factors, such as literacy. Describe the stakeholders and resources in the catchment area that can help implement the needed capacity development.

2. Based on the information and/or data currently available, document the prevalence of domestic and sexual violence.

3. Based on the information and/or data currently available, document the need to increase the capacity to implement, sustain, and improve

effective domestic and sexually violence services in the proposed catchment area that is consistent with the purpose of the program and the notice of funding opportunity announcement. Based on available data, describe the service gaps and other problems related to the response to domestic and sexual violence. Identify the source of the data. Documentation of need may come from a variety of qualitative and quantitative sources. Examples of data sources for the quantitative data that could be used are local epidemiologic data (Tribal Epidemiology Centers and/or Indian Health Services Trends) state data (*e.g.*, from state needs assessments), and/or national data (*e.g.*, Substance Abuse and Mental Health Services Administration, National Survey on Drug Use and Health) and/or national data (*e.g.*, National Center for Health Statistics, Centers for Disease Control reports, Department of Justice or Census data, and My Tribal Area from the U.S. Census Data). This list is not exhaustive; applicants may submit other valid data, as appropriate for the applicant's program.

4. Describe the existing health service gaps, barriers, and other systemic challenges related to the need for planning and capacity building and coordination of domestic and sexual violence services.

5. Describe potential project partners and community resources in the catchment area that can participate in the planning process and capacity building.

6. Affirm the goals of the project are consistent with priorities of the Tribal government or board of directors and that the governing body is in support of this application.

B. Project Narrative/Proposed Approach (20 Points)

The project narrative required components (listed as the five components (A–E) in "Requirements for Project Narrative") together should not exceed 10 single-spaced pages.

1. Describe the purpose of the proposed project, including a clear statement of goals and objectives. The proposed project narrative is required to address all eight objectives listed for DVPI Purpose Area #1 or Purpose Area #2. Describe how achievement of goals will increase system capacity to support the goals and objectives or activities for DVPI Purpose Area #1 or Purpose Area #2.

2. Describe how project activities will increase the capacity of the identified community to plan and improve the coordination of a collaborative service system for victims of domestic and

sexual violence. Describe anticipated barriers to progress of the project and how these barriers will be addressed.

3. Describe how the proposed project will address issues of diversity within the population of focus including age, race, gender, ethnicity, culture/cultural identity, language, sexual orientation, disability, and literacy.

4. Describe how the proposed project will address domestic violence and sexual assault in the communities being served.

5. Describe how the efforts of the proposed project will be coordinated with any other related Federal grants, including IHS, the Department of Justice (DOJ), Substance Abuse and Mental Health Services Administration (SAMHSA), or Bureau of Indian Affairs (BIA) services provided in the community (if applicable).

6. Provide a timeline chart depicting a realistic timeline for the entire project period showing key activities, milestones, and responsible staff. These key activities should include the requirements outlined in the chosen Purpose Area. [Note: The timeline chart should be part of the Project Narrative as specified in the "Requirements for Project Proposals" section. It should not be placed in as an attachment.]

7. If the applicant plans to include an advisory body in the project, describe its membership, roles and functions, and frequency of meetings.

8. Identify any other organization(s) that will participate in the proposed project. Describe their roles, responsibilities and demonstrate their commitment to the project. Include a list of these organizations as an attachment to the project proposal/application. In the attached list, indicate the organizations that the Tribe, Tribal organization or UIO has worked with or currently works with. [Note: The attachment will not count as part of the 10-page maximum.]

C. Organizational Capacity and Staffing/ Administration (15 Points)

1. Describe the management capability and experience of the applicant Tribe, Tribal organization, or UIO and other participating organizations in administering similar grants and projects.

2. Identify the department/division that will administer this project. Include a description of this entity, its function, and its placement within the organization (Tribe, Tribal organization, or UIO). If the program is to be managed by a consortium or Tribal organization, identify how the project office relates to the member community/communities.

3. Discuss the applicant Tribe, Tribal organization, or UIO experience, and capacity to provide culturally appropriate/competent services to the community and specific populations of focus.

4. Describe the resources available for the proposed project (e.g., facilities, equipment, information technology systems, and financial management systems).

5. Describe how project continuity will be maintained if/when there is a change in the operational environment (e.g., staff turnover, change in project leadership, change in elected officials) to ensure project stability over the life of the grant.

6. Provide a list of staff positions for the project, including the DVPI health staff, project director, project coordinator, and other key personnel, showing the role of each and their level of effort and qualifications. Demonstrate successful project implementation for the level of effort budgeted for the DVPI staff, project director, project coordinator, and other key staff.

7. Include position descriptions as *attachments* to the application for the behavioral health staff, project director, project coordinator, and all key personnel. Position descriptions should not exceed one page each. [Note: Attachments will not count against the 10 page maximum.]

8. For individuals that are currently on staff, include a biographical sketch (not to include personally identifiable information) for each individual that will be listed as the behavioral health staff, project director, project coordinator, and other key positions. Describe the experience of identified staff in domestic violence and sexual assault work in the community/communities. Include each biographical sketch as *attachments* to the project proposal/application. Biographical sketches should not exceed one page per staff member. Reviewers will not consider information past page one. [Note: Attachments will not count against the 10 page maximum.] Do not include any of the following:

- Personally Identifiable Information;
- Resumes; or
- Curriculum Vitae.

D. Local Data Collection Plan (20 Points)

(1) Utilizing the Local Data Collection Plan (LDGP) template, applicants should describe a plan for gathering data relevant to the DVPI Purpose Area #1 or Purpose Area #2 Objectives. This includes a plan for each activity that details:

- A data collection method, a data source, a data measurement tool,

identified staff for data management, and a data collection timeline.

- In addition, a narrative section after the template should describe how the applicant will submit the required data, how the applicant will monitor the data, and outline the applicant's ability to ensure accurate data tracking and reporting (e.g., submission of annual progress reporting requirements).

E. Budget and Budget Narrative (10 Points)

1. Include a line item budget for all expenditures identifying reasonable and allowable costs necessary to accomplish the goals and objectives as outlined in the project narrative for *Budget Year 1 only*. The budget should match the scope of work described in the project narrative for the *first budget year expenses only*.

2. The applicant must provide a budget narrative justification of the items included in the proposed line item budget supporting the mission and goals of DVPI.

3. Applicants should ensure that the budget and budget narrative are aligned with the project narrative. The Budget and Budget Narrative the applicant provides will be considered by reviewers in assessing the applicant's submission, along with the material in the Project Narrative.

4. The budget and budget narrative must not exceed four single-spaced pages.

Additional Documents Can Be Uploaded as Appendix Items in Grants.gov

- Work plan, logic model and/or time line for proposed objectives.
- Position descriptions for key staff.
- Resumes of key staff that reflect current duties.
- Consultant or contractor proposed scope of work and letter of commitment (if applicable).
- Current Indirect Cost Agreement.
- Organizational chart.
- Map of area identifying project location(s).
- Additional documents to support narrative (i.e., data tables, key news articles, etc.).

2. Review and Selection

Each application will be prescreened by the DGM staff for eligibility and completeness as outlined in the funding announcement. Applications that meet the eligibility criteria shall be reviewed for merit by the ORC based on evaluation criteria in this funding announcement. The ORC could be composed of both Tribal and Federal reviewers appointed by the IHS Program

to review and make recommendations on these applications. The technical review process ensures selection of quality projects in a national competition for limited funding. Incomplete applications and applications that are non-responsive to the eligibility criteria will not be referred to the ORC. The applicant will be notified via email of this decision by the Grants Management Officer of the DGM. Applicants will be notified by DGM, via email, to outline minor missing components (e.g. budget narratives, audit documentation, key contact form) needed for an otherwise complete application. All missing documents must be sent to DGM on or before the due date listed in the email of notification of missing documents required.

To obtain a minimum score for funding by the ORC, applicants must address all program requirements and provide all required documentation.

VI. Award Administration Information

1. Award Notices

The NoA is a legally binding document signed by the Grants Management Officer and serves as the official notification of the grant award. The NoA will be initiated by the DGM in our grant system, GrantSolutions (<https://www.grantsolutions.gov>). Each entity that is approved for funding under this announcement will need to request or have a user account in GrantSolutions in order to retrieve their NoA. The NoA is the authorizing document for which funds are dispersed to the approved entities and reflects the amount of Federal funds awarded, the purpose of the grant, the terms and conditions of the award, the effective date of the award, and the budget/project period.

Disapproved Applicants

Applicants who received a score less than the recommended funding level for approval, 65, and were deemed to be disapproved by the ORC, will receive an Executive Summary Statement from the IHS program office within 30 days of the conclusion of the ORC outlining the strengths and weaknesses of their application. The summary statement will be sent to the Authorized Organizational Representative that is identified on the face page (SF-424) of the application. The IHS program office will also provide additional contact information as needed to address questions and concerns as well as provide technical assistance if desired.

Approved But Unfunded Applicants

Approved but unfunded applicants that met the minimum scoring range and were deemed by the ORC to be "Approved", but were not funded due to lack of funding, will have their applications held by DGM for a period of one year. If additional funding becomes available during the course of FY 2017 the approved but unfunded application may be re-considered by the awarding program office for possible funding. The applicant will also receive an Executive Summary Statement from the IHS program office within 30 days of the conclusion of the ORC.

Note: Any correspondence other than the official NoA signed by an IHS grants management official announcing to the project director that an award has been made to their organization is not an authorization to implement their program on behalf of IHS.

2. Administrative Requirements

Grants are administered in accordance with the following regulations and policies:

A. The criteria as outlined in this program announcement.

B. Administrative Regulations for Grants:

- Uniform Administrative Requirements for HHS Awards, located at 45 CFR part 75.

C. Grants Policy:

- HHS Grants Policy Statement, Revised 01/07.

D. Cost Principles:

- Uniform Administrative Requirements for HHS Awards, "Cost Principles," located at 45 CFR part 75, subpart E.

E. Audit Requirements:

- Uniform Administrative Requirements for HHS Awards, "Audit Requirements," located at 45 CFR part 75, subpart F.

3. Indirect Costs

This section applies to all grant recipients that request reimbursement of indirect costs (IDC) in their grant application. In accordance with HHS Grants Policy Statement, Part II-27, IHS requires applicants to obtain a current IDC rate agreement prior to award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current rate covers the applicable grant activities under the current award's budget period. If the current rate is not on file with the DGM at the time of award, the IDC portion of the budget will be restricted. The restrictions remain in place until the current rate is provided to the DGM.

Generally, IDC rates for IHS grantees are negotiated with the Division of Cost Allocation (DCA) <https://rates.psc.gov/> and the Department of Interior (Interior Business Center) <https://www.doi.gov/ibc/services/finance/indirect-Cost-Services/indian-tribes>. For questions regarding the indirect cost policy, please call the Grants Management Specialist listed under "Agency Contacts" or the main DGM office at (301) 443-5204.

4. Reporting Requirements

The grantee must submit required reports consistent with the applicable deadlines. Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in one or both of the following: (1) The imposition of special award provisions; and (2) the non-funding or non-award of other eligible projects or activities. This requirement applies whether the delinquency is attributable to the failure of the grantee organization or the individual responsible for preparation of the reports. Per DGM policy, all reports are required to be submitted electronically by attaching them as a "Grant Note" in GrantSolutions. Personnel responsible for submitting reports will be required to obtain a login and password for GrantSolutions. Please see the Agency Contacts list in section VII for the systems contact information.

The reporting requirements for this program are noted below.

A. Progress Reports

Program progress reports are required to be submitted annually, within 30 days after the annual budget period ends. Progress reports will include an online submission of standard questions that will be provided to each grantee. Additional information for reporting and associated requirements will be included in the "Programmatic Terms and Conditions" in the official NoA, if funded.

A final program progress report must be submitted within 90 days of expiration of the budget/project period.

B. Financial Reports

Federal Financial Report (FFR or SF-425), Cash Transaction Reports are due 30 days after the close of every calendar quarter to the Payment Management Services, HHS at <https://pms.psc.gov>. It is recommended that the applicant also send a copy of the FFR (SF-425) report

to the Grants Management Specialist. Failure to submit timely reports may cause a disruption in timely payments to the organization.

Grantees are responsible and accountable for accurate information being reported on all required reports: The Progress Reports and Federal Financial Report.

C. Federal Sub-Award Reporting System (FSRS)

This award may be subject to the Transparency Act sub-award and executive compensation reporting requirements of 2 CFR part 170.

The Transparency Act requires the OMB to establish a single searchable database, accessible to the public, with information on financial assistance awards made by Federal agencies. The Transparency Act also includes a requirement for recipients of Federal grants to report information about first-tier sub-awards and executive compensation under Federal assistance awards.

IHS has implemented a Term of Award into all IHS Standard Terms and Conditions, NoAs and funding announcements regarding the FSRS reporting requirement. This IHS Term of Award is applicable to all IHS grant and cooperative agreements issued on or after October 1, 2010, with a \$25,000 sub-award obligation dollar threshold met for any specific reporting period. Additionally, all new (discretionary) IHS awards (where the project period is made up of more than one budget period) and where: (1) The project period start date was October 1, 2010 or after and (2) the primary awardee will have a \$25,000 sub-award obligation dollar threshold during any specific reporting period will be required to address the FSRS reporting.

For the full IHS award term implementing this requirement and additional award applicability information, visit the DGM Grants Policy Web site at: <http://www.ihs.gov/dgm/policytopics/>.

D. Compliance With Executive Order 13166 Implementation of Services Accessibility Provisions for All Grant Application Packages and Funding Opportunity Announcements

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your

programs are accessible to persons with limited English proficiency. HHS provides guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see <http://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/guidance-federal-financial-assistance-recipients-title-VI/>.

The HHS Office for Civil Rights (OCR) also provides guidance on complying with civil rights laws enforced by HHS. Please see <http://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html>; and <http://www.hhs.gov/civil-rights/index.html>. Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see <http://www.hhs.gov/civil-rights/for-individuals/disability/index.html>.

Please contact the HHS OCR for more information about obligations and prohibitions under federal civil rights laws at <https://www.hhs.gov/ocr/about-us/contact-us/index.html> or call 1-800-368-1019 or TDD 1-800-537-7697.

Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at <https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53>.

Pursuant to 45 CFR 80.3(d), an individual shall not be deemed subjected to discrimination by reason of his/her exclusion from benefits limited by federal law to individuals eligible for benefits and services from the IHS.

Recipients will be required to sign the HHS-690 Assurance of Compliance form which can be obtained from the following Web site: <http://www.hhs.gov/sites/default/files/forms/hhs-690.pdf>, and send it directly to the: U.S. Department of Health and Human Services, Office of Civil Rights, 200 Independence Ave. SW., Washington, DC 20201.

F. The IHS is required to review and consider any information about the 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 \$150,000) over the period of performance. An applicant may review and comment on any information about itself that a federal awarding agency

previously entered. IHS 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 45 CFR 75.205.

As required by 45 CFR part 75 Appendix XII of the Uniform Guidance, non-federal entities (NFEs) are required to disclose in FAPIIS any information about criminal, civil, and administrative proceedings, and/or affirm that there is no new information to provide. This applies to NFEs that receive federal awards (currently active grants, cooperative agreements, and procurement contracts) greater than \$10,000,000 for any period of time during the period of performance of an award/project.

Mandatory Disclosure Requirements

As required by 2 CFR part 200 of the Uniform Guidance, and the HHS implementing regulations at 45 CFR part 75, effective January 1, 2016, the IHS must require a non-federal entity or an applicant for a federal award to disclose, in a timely manner, in writing to the IHS or pass-through entity all violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award.

Submission is required for all applicants and recipients, in writing, to the IHS and to the HHS Office of Inspector General all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. 45 CFR 75.113.

Disclosures must be sent in writing to: U.S. Department of Health and Human Services, Indian Health Service, Division of Grants Management, ATTN: Robert Tarwater, Director, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857. (Include "Mandatory Grant Disclosures" in subject line), Office: (301) 443-5204, Fax: (301) 594-0899, Email: Robert.Tarwater@ihs.gov

And U.S. Department of Health and Human Services, Office of Inspector General, ATTN: Mandatory Grant Disclosures, Intake Coordinator, 330 Independence Avenue SW., Cohen Building, Room 5527, Washington, DC 20201, URL: <http://oig.hhs.gov/fraud/report-fraud/index.asp>. (Include "Mandatory Grant Disclosures" in subject line), Fax: (202) 205-0604 (Include "Mandatory Grant Disclosures" in subject line) or Email: MandatoryGranteeDisclosures@oig.hhs.gov.

Failure to make required disclosures can result in any of the remedies described in 45 CFR 75.371 Remedies for noncompliance, including suspension or debarment (see 2 CFR parts 180 & 376 and 31 U.S.C. 3321).

VII. Agency Contacts

1. Questions on the programmatic issues may be directed to: Selina T. Keryte, Public Health Analyst, DVPI National Coordinator, Division of Behavioral Health, 5600 Fishers Lane, Mail Stop: 08N34-A, Rockville, MD 20857, *Phone:* (301) 443-7064, *Fax:* (301) 594-6213, *Email:* Selina.keryte@ihs.gov
2. Questions on grants management and fiscal matters may be directed to: Andrew Diggs, Grants Management Specialist, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, *Phone:* (301) 443-2241, *Fax:* (301) 594-0899, *Email:* Andrew.Diggs@ihs.gov
3. Questions on systems matters may be directed to: Paul Gettys, Grant Systems Coordinator, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, *Phone:* (301) 443-2114; or the DGM main line: (301) 443-5204, *Fax:* (301) 594-0899, *Email:* Paul.Gettys@ihs.gov

VIII. Other Information

The Public Health Service strongly encourages all cooperative agreement and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the HHS mission to protect and advance the physical and mental health of the American people.

Dated: July 21, 2017.

Michael D. Weahkee,
*RADM, Assistant Surgeon General, U.S.
 Public Health Service, Acting Director, Indian
 Health Service.*

[FR Doc. 2017-15933 Filed 7-27-17; 8:45 am]

BILLING CODE 4165-16-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Notice of Delivery Area Designation for the Pamunkey Indian Tribe

AGENCY: Indian Health Service, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that Indian Health Service (IHS) is establishing the geographic boundaries of the Purchased/Referred Care Delivery Area (PRCDA) (formerly Contract Health Service Delivery Area or CHSDA) for the newly recognized Pamunkey Indian Tribe. The Pamunkey Indian Tribe's PRCDA is to be comprised of Caroline; Hanover; Henrico; King William; King and Queen; and New Kent Counties and the independent city of Richmond in the State of Virginia. The six counties and the one independent city listed are being designated administratively as the PRCDA for the Pamunkey Indian Tribe.

DATES: This notice is effective as of August 28, 2017.

ADDRESSES: This notice can be found at <https://www.federalregister.gov>. Written requests for information or comments submitted by postal mail or delivery should be addressed to: Evonne Barnett-Barnes, Management Analyst, Indian Health Service, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Terri Schmidt, Acting Director, Office of Resource Access and Partnerships, Indian Health Service, 5600 Fishers Lane, Mail Stop: 10E85C, Rockville, MD 20857, (301) 443-2694 (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: The IHS currently provides services under regulations in effect on September 15, 1987, and IHS republished at 42 CFR part 136, subparts A-C. Many of the newly recognized Tribes do not have reservations and either Congress has legislatively designated counties to serve as PRCDA's or the Director, IHS, exercised reasonable administrative discretion to designate PRCDA's to effectuate the intent of Congress for these Tribes. The Director, IHS, publishes a notice in the FR when there are revisions or updates to the list of PRCDA's, including the PRCDA's for newly recognized Tribes.

At 42 CFR 136 subpart C, a PRCDA is defined as the geographic area within which PRC will be made available by the IHS to members of an identified Indian community who reside in the area. The regulations provide that, unless otherwise designated, a PRCDA shall consist of a county which includes all or part of a reservation and any county or counties which have a common boundary with the reservation (42 CFR 136.22(a)(6)).

Residence within a PRCDA by a person who is within the scope of the Indian health program, as set forth in 42 CFR 136.12 creates no legal entitlement

to PRC but only potential eligibility for services. Services needed but not available at an IHS/Tribal facility are provided under the PRC program depending on the availability of funds, the person's relative medical priority, and the actual availability and accessibility of alternate resources in accordance with the regulations.

In the notice published on July 08, 2015 (80 FR 39144), the Pamunkey Indian Tribe was officially recognized as an Indian Tribe within the meaning of Federal law. The purpose of this FR notice is to notify the public of the establishment of the Pamunkey Indian Tribe's PRCDA to include Caroline; Hanover; Henrico; King William; King and Queen; and New Kent Counties and the independent city of Richmond in the State of Virginia.

Under 42 CFR 136.23 those otherwise eligible Indians who do not reside on a reservation but reside within a PRCDA must be either members of the Tribe or maintain close economic and social ties with the Tribe. In this case, the Tribe estimated the eligible user population to be 337 enrolled Pamunkey members who are actively involved with the Tribe.

The Pamunkey Indian Tribe has a state-recognized reservation in King William County, Virginia. A significant number of the Pamunkey eligible user population also reside in the counties of Caroline; Hanover; Henrico; King and Queen; and New Kent Counties and Richmond (Independent City) in the State of Virginia. These six counties and the independent city of Richmond form a contiguous area that does not overlap with any other Tribe's PRCDA. Most of the counties listed have a common boundary with King William County, where the Tribe's state-recognized reservation is located. Henrico County and the independent city of Richmond do not; however, IHS construes the provision set forth in 42 CFR 136.23(a)(6) to apply only to federal Indian reservations and not to state-recognized reservations. Consequently, IHS is administratively establishing the Tribe's PRCDA in accordance with the congressional intention to provide health services "on or near," rather than the specific provision set forth in 42 CFR 136.23(a)(6).

It is important for the Pamunkey Indian Tribe to be able to deliver health care services to Tribal members residing in these six counties and one independent city. The Tribe believes eligible Tribal members are living in each of the counties of the PRCDA, as well as the independent city of Richmond, and that these Tribal members should be eligible for PRC.

The financial resources required to meet the immediate needs of the Tribal members residing in the six counties and the one independent city were determined by the IHS and will be

placed in the Nashville Area PRC budget.

This notice does not contain reporting or recordkeeping requirements subject to prior approval by the Office of

Management and Budget under the Paperwork Reduction Act of 1980.

PURCHASED/REFERRED CARE DELIVERY AREAS

Tribe/reservation	County/state
Ak Chin Indian Community	Pinal, AZ.
Alabama-Coushatta Tribes of Texas	Polk, TX ¹ .
Alaska	Entire State ² .
Arapahoe Tribe of the Wind River Reservation, Wyoming	Hot Springs, WY, Fremont, WY, Sublette, WY.
Aroostook Band of Micmacs	Aroostook, ME ³ .
Assiniboine and Sioux Tribes of the Fort Peck Indian Reservation, Montana.	Daniels, MT, McCone, MT, Richland, MT, Roosevelt, MT, Sheridan, MT, Valley, MT.
Bad River Band of the Lake Superior Tribe of Chippewa Indians of the Bad River Reservation, Wisconsin.	Ashland, WI, Iron, WI.
Bay Mills Indian Community, Michigan	Chippewa, MI.
Blackfeet Tribe of the Blackfeet Indian Reservation of Montana	Glacier, MT, Pondera, MT.
Brigham City Intermountain School Health Center, Utah	(4).
Burns Paiute Tribe	Harney, OR.
California	Entire State, except for the counties listed in the footnote ⁵ .
Catawba Indian Nation	All Counties in SC ⁶ , Cabarrus, NC, Cleveland, NC, Gaston, NC, Mecklenburg, NC, Rutherford, NC, Union, NC.
Cayuga Nation	Alleghany, NY ⁷ , Cattaraugus, NY, Chautauqua, NY, Erie, NY, Warren, PA.
Cheyenne River Sioux Tribe of the Cheyenne River Reservation, South Dakota.	Corson, SD, Dewey, SD, Haakon, SD, Meade, SD, Perkins, SD, Potter, SD, Stanley, SD, Sully, SD, Walworth, SD, Ziebach, SD.
Chippewa-Cree Indians of the Rocky Boy's Reservation, Montana	Chouteau, MT, Hill, MT, Liberty, MT.
Chitimacha Tribe of Louisiana	St. Mary Parish, LA.
Cocopah Tribe of Arizona	Yuma, AZ, Imperial, CA.
Coeur D'Alene Tribe	Benewah, ID, Kootenai, ID, Latah, ID, Spokane, WA, Whitman, WA.
Colorado River Indian Tribes of the Colorado River Indian Reservation, Arizona and California.	La Paz, AZ, Riverside, CA, San Bernardino, CA, Yuma, AZ.
Confederated Salish and Kootenai Tribes of the Flathead Reservation	Flathead, MT, Lake, MT, Missoula, MT, Sanders, MT.
Confederated Tribes and Bands of the Yakama Nation	Klickitat, WA, Lewis, WA, Skamania, WA ⁸ , Yakima, WA.
Confederated Tribes of Siletz Indians of Oregon	Benton, OR ⁹ , Clackamas, OR, Lane, OR, Lincoln, OR, Linn, OR, Marion, OR, Multnomah, OR, Polk, OR, Tillamook, OR, Washington, OR, Yamhill, OR.
Confederated Tribes of the Chehalis Reservation	Grays Harbor, WA, Lewis, WA, Thurston, WA.
Confederated Tribes of the Colville Reservation	Chelan, WA ¹⁰ , Douglas, WA, Ferry, WA, Grant, WA, Lincoln, WA, Okanogan, WA, Stevens, WA.
Confederated Tribes of the Coos, Lower Umpqua and Siuslaw Indians	Coos, OR ¹¹ , Curry, OR, Douglas, OR, Lane, OR, Lincoln, OR.
Confederated Tribes of the Goshute Reservation, Nevada and Utah	Nevada, Juab, UT, Toole, UT.
Confederated Tribes of the Grand Ronde Community of Oregon	Marion, OR, Multnomah, OR, Polk, OR ¹² , Tillamook, OR, Washington, OR, Yamhill, OR.
Confederated Tribes of the Umatilla Indian Reservation	Umatilla, OR, Union, OR.
Confederated Tribes of the Warm Springs Reservation of Oregon	Clackamas, OR, Jefferson, OR, Linn, OR, Marion, OR, Wasco, OR.
Coquille Indian Tribe	Coos, OR, Curry, OR, Douglas, OR, Jackson, OR, Lane, OR.
Coushatta Tribe of Louisiana	Allen Parish, LA, Elton, LA ¹³ .
Cow Creek Band of Umpqua Tribe of Indians	Coos, OR ¹⁴ , Deshutes, OR, Douglas, OR, Jackson, OR, Josephine, OR, Klamath, OR, Lane, OR.
Cowlitz Indian Tribe	Clark, WA, Cowlitz, WA, King, WA, Lewis, WA, Peirce, WA, Skamania, WA, Thurston, WA, Columbia, OR ¹⁵ , Kittitas, WA, Wahkiakum, WA.
Crow Creek Sioux Tribe of the Crow Creek Reservation, South Dakota	Brule, SD, Buffalo, SD, Hand, SD, Hughes, SD, Hyde, SD, Lyman, SD, Stanley, SD.
Crow Tribe of Montana	Big Horn, MT, Carbon, MT, Treasure, MT ¹⁶ , Yellowstone, MT, Big Horn, WY, Sheridan, WY.
Eastern Band of Cherokee Indians	Cherokee, NC, Graham, NC, Haywood, NC, Jackson, NC, Swain, NC.
Eastern Shoshone Tribe of the Wind River Reservation, Wyoming	Hot Springs, WY, Fremont, WY, Sublette, WY.
Flandreau Santee Sioux Tribe of South Dakota	Moody, SD.
Forest County Potawatomi Community, Wisconsin	Forest, WI, Marinette, WI, Oconto, WI.
Fort Belknap Indian Community of the Fort Belknap Reservation of Montana.	Blaine, MT, Phillips, MT.
Fort McDermitt Paiute and Shoshone Tribes of the Fort McDermitt Indian Reservation, Nevada and Oregon.	Nevada, Malheur, OR.
Fort McDowell Yavapai Nation, Arizona	Maricopa, AZ.
Fort Mojave Indian Tribe of Arizona, California and Nevada	Nevada, Mohave, AZ, San Bernardino, CA.
Gila River Indian Community of the Gila River Indian Reservation, Arizona.	Maricopa, AZ, Pinal, AZ.
Grand Traverse Band of Ottawa and Chippewa Indians, Michigan	Antrim, MI ¹⁷ , Benzie, MI, Charlevoix, MI, Grand Traverse, MI, Leelanau, MI, Manistee, MI.
Hannahville Indian Community, Michigan	Delta, MI, Menominee, MI.
Haskell Indian Health Center	Douglas, KS ¹⁸ .

PURCHASED/REFERRED CARE DELIVERY AREAS—Continued

Tribe/reservation	County/state
Havasupai Tribe of the Havasupai Reservation, Arizona	Coconino, AZ.
Ho-Chunk Nation of Wisconsin	Adams, WI ¹⁹ , Clark, WI, Columbia, WI, Crawford, WI, Dane, WI, Eau Clarrie, WI, Houston, MN, Jackson, WI, Juneau, WI, La Crosse, WI, Marathon, WI, Monroe, WI, Sauk, WI, Shawano, WI, Vernon, WI, Wood, WI.
Hoh Indian Tribe	Jefferson, WA.
Hopi Tribe of Arizona	Apache, AZ, Coconino, AZ, Navajo, AZ.
Houlton Band of Maliseet Indians	Aroostook, ME ²⁰ .
Hualapai Indian Tribe of the Hualapai Indian Reservation, Arizona	Coconino, AZ, Mohave, AZ, Yavapai, AZ.
Iowa Tribe of Kansas and Nebraska	Brown, KS, Doniphan, KS, Richardson, NE.
Jamestown S'Klallam Tribe	Clallam, WA, Jefferson, WA.
Jena Band of Choctaw Indians	Grand Parish, LA ²¹ , LaSalle Parish, LA, Rapides, LA.
Jicarilla Apache Nation, New Mexico	Archuleta, CO, Rio Arriba, NM, Sandoval, NM.
Kaibab Band of Paiute Indians of the Kaibab Indian Reservation, Ari- zona.	Coconino, AZ, Mohave, AZ, Kane, UT.
Kalispel Indian Community of the Kalispel Reservation	Pend Oreille, WA, Spokane, WA.
Kewa Pueblo, New Mexico	Sandoval, NM, Santa Fe, NM.
Keweenaw Bay Indian Community, Michigan	Baraga, MI, Houghton, MI, Ontonagon, MI.
Kickapoo Traditional Tribe of Texas	Maverick, TX ²² .
Kickapoo Tribe of Indians of the Kickapoo Reservation in Kansas	Brown, KS, Jackson, KS.
Klamath Tribes	Klamath, OR ²³ .
Koi Nation of Northern California (formerly known as Lower Lake Rancheria, California).	Lake, CA, Sonoma, CA ²⁴ .
Kootenai Tribe of Idaho	Boundary, ID.
Lac Courte Oreilles Band of Superior Chippewa Indians of Wisconsin ..	Sawyer, WI.
Lac du Flambeau Band of Lake Superior Chippewa Indians of the Lac du Flambeau Reservation of Wisconsin.	Iron, WI, Oneida, WI, Vilas, WI.
Lac Vieux Desert Band of Lake Superior Chippewa Indians of Michigan	Gogebic, MI.
Little River Band of Ottawa Indians, Michigan	Kent, MI ²⁵ , Muskegon, MI, Newaygo, MI, Oceana, MI, Ottawa, MI, Manistee, MI, Mason, MI, Wexford, MI, Lake, MI.
Little Traverse Bay Bands of Odawa Indians, Michigan	Alcona, MI ²⁶ , Alger, MI, Alpena, MI, Antrim, MI, Benzie, MI, Charlevoix, MI, Cheboygan, MI, Chippewa, MI, Crawford, MI, Delta, MI, Emmet, MI, Grand Traverse, MI, Iosco, MI, Kalkaska, MI, Leelanau, MI, Luce, MI, Mackinac, MI, Manistee, MI, Missaukee, MI, Montmorency, MI, Ogemaw, MI, Oscoda, MI, Otsego, MI, Presque Isle, MI, Schoolcraft, MI, Roscommon, MI, Wexford, MI.
Lower Brule Sioux Tribe of the Lower Brule Reservation, South Dakota	Brule, SD, Buffalo, SD, Hughes, SD, Lyman, SD, Stanley, SD.
Lower Elwha Tribal Community	Clallam, WA.
Lower Sioux Indian Community in the State of Minnesota	Redwood, MN, Renville, MN.
Lummi Tribe of the Lummi Reservation	Whatcom, WA.
Makah Indian Tribe of the Makah Indian Reservation	Clallam, WA.
Mashantucket Pequot Indian Tribe	New London, CT ²⁷ .
Mashpee Wampanoag Tribe	Barnstable, MA, Bristol, MA, Norfolk, MA, Plymouth, MA, Suffolk, MA ²⁸ .
Match-e-be-nash-she-wish Band of Pottawatomi Indians of Michigan	Allegan, MI ²⁹ , Barry, MI, Kalamazoo, MI, Kent, MI, Ottawa, MI.
Menominee Indian Tribe of Wisconsin	Langlade, WI, Menominee, WI, Oconto, WI, Shawano, WI.
Mescalero Apache Tribe of the Mescalero Reservation, New Mexico	Chaves, NM, Lincoln, NM, Otero, NM.
Miccosukee Tribe of Indians	Broward, FL, Collier, FL, Miami-Dade, FL, Hendry, FL.
Minnesota Chippewa Tribe, Minnesota, Bois Forte Band (Nett Lake)	Itasca, MN, Koochiching, MN, St. Louis, MN.
Minnesota Chippewa Tribe, Minnesota, Fond du Lac Band	Carlton, MN, St. Louis, MN.
Minnesota Chippewa Tribe, Minnesota, Grand Portage Band	Cook, MN.
Minnesota Chippewa Tribe, Minnesota, Leech Lake Band	Beltrami, MN, Cass, MN, Hubbard, MN, Itasca, MN.
Minnesota Chippewa Tribe, Minnesota, Mille Lacs Band	Aitkin, MN, Kanebec, MN, Mille Lacs, MN, Pine, MN.
Minnesota Chippewa Tribe, Minnesota, White Earth Band	Becker, MN, Clearwater, MN, Mahnomen, MN, Norman, MN, Polk, MN.
Mississippi Band of Choctaw Indians	Attala, MS, Jasper, MS ³⁰ , Jones, MS, Kemper, MS, Leake, MS, Neshoba, MS, Newton, MS, Noxubee, MS ³¹ , Scott, MS ³² , Winston, MS.
Mohegan Tribe of Indians of Connecticut	Fairfield, CT, Hartford, CT, Litchfield, CT, Middlesex, CT, New Haven, CT, New London, CT, Tolland, CT, Windham, CT.
Muckleshoot Indian Tribe	King, WA, Pierce, WA.
Narragansett Indian Tribe	Washington, RI ³³ .
Navajo Nation, Arizona, New Mexico, & Utah	Apache, AZ, Bernalillo, NM, Cibola, NM, Coconino, AZ, Kane, UT, McKinley, NM, Montezuma, CO, Navajo, AZ, Rio Arriba, NM, Sandoval, NM, San Juan, NM, San Juan, UT, Socorro, NM, Valen- cia, NM.
Nevada	Entire State ³⁴ .
Nez Perce Tribe	Clearwater, ID, Idaho, ID, Latah, ID, Lewis, ID, Nez Perce, ID.
Nisqually Indian Tribe	Pierce, WA, Thurston, WA.
Nooksack Indian Tribe	Whatcom, WA.
Northern Cheyenne Tribe of the Northern Cheyenne Indian Reserva- tion, Montana.	Big Horn, MT, Carter, MT ³⁵ , Rosebud, MT.
Northwestern Band of Shoshone Nation	Box Elder, UT ³⁶ .

PURCHASED/REFERRED CARE DELIVERY AREAS—Continued

Tribe/reservation	County/state
Nottawaseppi Huron Band of the Pottawatomi, Michigan	Allegan, MI ³⁷ , Barry, MI, Branch, MI, Calhoun, MI, Kalamazoo, MI, Kent, MI, Ottawa, MI.
Oglala Sioux Tribe	Bennett, SD, Cherry, NE, Custer, SD, Dawes, NE, Fall River, SD, Jackson, SD ³⁸ , Mellette, SD, Pennington, SD, Shannon, SD, Sheridan, NE, Todd, SD.
Ohkay Owingeh, New Mexico	Rio Arriba, NM.
Oklahoma	Entire State ³⁹ .
Omaha Tribe of Nebraska	Burt, NE, Cuming, NE, Monona, IA, Thurston, NE, Wayne, NE.
Oneida Nation	Brown, WI, Outagamie, WI.
Oneida Nation of New York	Chenango, NY, Cortland, NY, Herkimer, NY, Madison, NY, Oneida, NY, Onondaga, NY.
Onondaga Nation	Onondaga, NY.
Paiute Indian Tribe of Utah	Iron, UT ⁴⁰ , Millard, UT, Sevier, UT, Washington, UT.
Pamunkey Indian Tribe	Caroline, Hanover, Henrico, King William, King and Queen, New Kent, Richmond (Independent City) ⁴¹ .
Pascua Yaqui Tribe of Arizona	Pima, AZ ⁴² .
Passamaquoddy Tribe	Aroostook, ME ^{43 44} , Hancock, ME ⁴⁵ , Washington, ME.
Penobscot Nation	Aroostook, ME ⁴⁶ , Penobscot, ME.
Poarch Band of Creeks	Baldwin, AL ⁴⁷ , Elmore, AL, Escambia, AL, Mobile, AL, Monroe, AL, Escambia, FL.
Pokagon Band of Pottawatomi Indians, Michigan and Indiana	Allegan, MI ⁴⁸ , Berrien, MI, Cass, MI, Elkhart, IN, Kosciusko, IN, La Porte, IN, Marshall, IN, St. Joseph, IN, Starke, IN, Van Buren, MI.
Ponca Tribe of Nebraska	Boyd, NE ⁴⁹ , Burt, NE, Charles Mix, SD, Douglas, NE, Hall, NE, Holt, NE, Knox, NE, Lancaster, NE, Madison, NE, Platte, NE, Pottawatomie, IA, Sarpy, NE, Stanton, NE, Wayne, NE, Woodbury, IA.
Port Gamble S'Klallam Tribe	Kitsap, WA.
Prairie Band of Pottawatomi Nation	Jackson, KS.
Prairie Island Indian Community in the State of Minnesota	Goodhue, MN.
Pueblo of Acoma, New Mexico	Cibola, NM.
Pueblo of Cochiti, New Mexico	Sandoval, NM, Santa Fe, NM.
Pueblo of Isleta, New Mexico	Bernalillo, NM, Tarrant, NM, Valencia, NM.
Pueblo of Jemez, New Mexico	Sandoval, NM.
Pueblo of Laguna, New Mexico	Bernalillo, NM, Cibola, NM, Sandoval, NM, Valencia, NM.
Pueblo of Nambe, New Mexico	Santa Fe, NM.
Pueblo of Picuris, New Mexico	Taos, NM.
Pueblo of Pojoaque, New Mexico	Rio Arriba, NM, Santa Fe, NM.
Pueblo of San Felipe, New Mexico	Sandoval, NM.
Pueblo of San Ildefonso, New Mexico	Los Alamos, NM, Rio Arriba, NM, Sandoval, NM, Santa Fe, NM.
Pueblo of Sandia, New Mexico	Bernalillo, NM, Sandoval, NM.
Pueblo of Santa Ana, New Mexico	Sandoval, NM.
Pueblo of Santa Clara, New Mexico	Los Alamos, NM, Sandoval, NM, Santa Fe, NM.
Pueblo of Taos, New Mexico	Colfax, NM, Taos, NM.
Pueblo of Tesuque, Mexico	Santa Fe, NM.
Pueblo of Zia, New Mexico	Sandoval, NM.
Puyallup Tribe of the Puyallup Reservation	King, WA, Pierce, WA, Thurston, WA.
Quechan Tribe of the Fort Yuma Indian Reservation, Arizona and California	Yuma, AZ, Imperial, CA.
Quileute Tribe of the Quileute Reservation	Clallam, WA, Jefferson, WA.
Quinault Indian Nation	Grays Harbor, WA, Jefferson, WA.
Rapid City, South Dakota	Pennington, SD ⁵⁰ .
Red Cliff Band of Lake Superior Chippewa Indians of Wisconsin	Bayfield, WI.
Red Lake Band of Chippewa Indians, Minnesota	Beltrami, MN, Clearwater, MN, Koochiching, MN, Lake of the Woods, MN, Marshall, MN, Pennington, MN, Polk, MN, Roseau, MN.
Rosebud Sioux Tribe of the Rosebud Indian Reservation, South Dakota	Bennett, SD, Cherry, NE, Gregory, SD, Lyman, SD, Mellette, SD, Todd, SD, Tripp, SD.
Sac & Fox Nation of Missouri in Kansas and Nebraska	Brown, KS, Richardson, NE.
Sac & Fox Tribe of the Mississippi in Iowa	Tama, IA.
Saginaw Chippewa Indian Tribe of Michigan	Arenac, MI ⁵¹ , Clare, MI, Isabella, MI, Midland, MI, Missaukee, MI.
Saint Regis Mohawk Tribe	Franklin, NY, St. Lawrence, NY.
Salt River Pima-Maricopa Indian Community of the Salt River Reservation, Arizona	Maricopa, AZ.
Samish Indian Nation	Clallam, WA ⁵² , Island, WA, Jefferson, WA, King, WA, Kitsap, WA, Pierce, WA, San Juan, WA, Skagit, WA, Snohomish, WA, Whatcom, WA.
San Carlos Apache Tribe of the San Carlos Reservation, Arizona	Apache, AZ, Cochise, AZ, Gila, AZ, Graham, AZ, Greenlee, AZ, Pinal, AZ.
San Juan Southern Paiute Tribe of Arizona	Coconino, AZ, San Juan, UT.
Santee Sioux Nation, Nebraska	Bon Homme, SD, Knox, NE.
Sauk-Suiattle Indian Tribe	Snohomish, WA, Skagit, WA.
Sault Ste. Marie Tribe of Chippewa Indians, Michigan	Alger, MI ⁵³ , Chippewa, MI, Delta, MI, Luce, MI, Mackinac, MI, Marquette, MI, Schoolcraft, MI.

PURCHASED/REFERRED CARE DELIVERY AREAS—Continued

Tribe/reservation	County/state
Seminole Tribe of Florida	Broward, FL, Collier, FL, Miami-Dade, FL, Glades, FL, Hendry, FL.
Seneca Nation of Indians	Alleghany, NY, Cattaraugus, NY, Chautauqua, NY, Erie, NY, Warren, PA.
Shakopee Mdewakanton Sioux Community of Minnesota	Scott, MN.
Shinnecock Indian Nation	Nassau, NY ⁵⁴ , Suffolk, NY.
Shoalwater Bay Tribe of the Shoalwater Bay Indian Reservation	Pacific, WA.
Shoshone-Bannock Tribes of the Fort Hall Reservation	Bannock, ID, Bingham, ID, Caribou, ID, Lemhi, ID ⁵⁵ , Power, ID.
Shoshone-Paiute Tribes of the Duck Valley Reservation, Nevada	Nevada, Owyhee, ID.
Sisseton-Wahpeton Oyate of the Lake Traverse Reservation, South Dakota	Codington, SD, Day, SD, Grant, SD, Marshall, SD, Richland, ND, Roberts, SD, Sargent, ND, Traverse, MN.
Skokomish Indian Tribe	Mason, WA.
Skull Valley Band of Goshute Indians of Utah	Tooele, UT.
Snoqualmie Indian Tribe	King, WA ⁵⁶ , Snohomish, WA, Pierce, WA, Island, WA, Mason, WA.
Sokaogon Chippewa Community, Wisconsin	Forest, WI.
Southern Ute Indian Tribe of the Southern Ute Reservation, Colorado ..	Archuleta, CO, La Plata, CO, Montezuma, CO, Rio Arriba, NM, San Juan, NM.
Spirit Lake Tribe, North Dakota	Benson, ND, Eddy, ND, Nelson, ND, Ramsey, ND.
Spokane Tribe of the Spokane Reservation	Ferry, WA, Lincoln, WA, Stevens, WA.
Squaxin Island Tribe of the Squaxin Island Reservation	Mason, WA.
St. Croix Chippewa Indians of Wisconsin	Barron, WI, Burnett, WI, Pine, MN, Polk, WI, Washburn, WI.
Standing Rock Sioux Tribe of North & South Dakota	Adams, ND, Campbell, SD, Corson, SD, Dewey, SD, Emmons, ND, Grant, ND, Morton, ND, Perkins, SD, Sioux, ND, Walworth, SD, Ziebach, SD.
Stillaguamish Tribe of Indians of Washington	Snohomish, WA.
Stockbridge Munsee Community, Wisconsin	Menominee, WI, Shawano, WI.
Suquamish Indian Tribe of the Port Madison Reservation	Kitsap, WA.
Swinomish Indian Tribal Community	Skagit, WA.
Tejon Indian Tribe	Kern, CA ⁵⁷ .
Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota ..	Dunn, ND, Mercer, ND, McKenzie, ND, McLean, ND, Mountrail, ND, Ward, ND.
Tohono O'odham Nation of Arizona	Maricopa, AZ, Pima, AZ, Pinal, AZ.
Tonawanda Band of Seneca	Genesee, NY, Erie, NY, Niagara, NY.
Tonto Apache Tribe of Arizona	Gila, AZ.
Trenton Service Unit, North Dakota and Montana	Divide, ND ⁵⁸ , McKenzie, ND, Williams, ND, Richland, MT, Roosevelt, MT, Sheridan, MT.
Tulalip Tribes of Washington	Snohomish, WA.
Tunica-Biloxi Indian Tribe	Avoyelles, LA, Rapides, LA ⁵⁹ .
Turtle Mountain Band of Chippewa Indians of North Dakota	Rolette, ND.
Tuscarora Nation	Niagara, NY.
Upper Sioux Community, Minnesota	Chippewa, MN, Yellow Medicine, MN.
Upper Skagit Indian Tribe	Skagit, WA.
Ute Indian Tribe of the Uintah & Ouray Reservation, Utah	Carbon, UT, Daggett, UT, Duchesne, UT, Emery, UT, Grand, UT, Rio Blanco, CO, Summit, UT, Uintah, UT, Utah, UT, Wasatch, UT.
Ute Mountain Ute Tribe	Apache, AZ, La Plata, CO, Montezuma, CO, San Juan, NM, San Juan, UT.
Wampanoag Tribe of Gay Head (Aquinnah)	Dukes, MA ⁶⁰ , Barnstable, MA, Bristol, MA, Norfolk, MA, Plymouth, MA, Suffolk, MA ⁶¹ .
Washoe Tribe of Nevada & California	Nevada, California except for the counties listed in footnote.
White Mountain Apache Tribe of the Fort Apache Reservation, Arizona ..	Apache, AZ, Coconino, AZ, Gila, AZ, Graham, AZ, Greenlee, AZ, Navajo, AZ.
Wilton Rancheria, California	Sacramento, CA ⁶² .
Winnebago Tribe of Nebraska	Dakota, NE, Dixon, NE, Monona, IA, Thurston, NE, Wayne, NE, Woodbury, IA.
Yankton Sioux Tribe of South Dakota	Bon Homme, SD, Boyd, NE, Charles Mix, SD, Douglas, SD, Gregory, SD, Hutchinson, SD, Knox, NE.
Yavapai-Apache Nation of the Camp Verde Indian Reservation, Arizona ..	Yavapai, AZ.
Yavapai-Prescott Indian Tribe	Yavapai, AZ.
Ysleta Del Sur Pueblo of Texas	El Paso, TX ⁶³ .
Zuni Tribe of the Zuni Reservation, New Mexico	Apache, AZ, Cibola, NM, McKinley, NM, Valencia, NM.

¹ Public Law 100–89, Restoration Act for Ysleta Del Sur and Alabama and Couthatta Tribes of Texas establishes service areas for “members of the Tribe” by sections 101(3) and 105(a) for the Pueblo and sections 201(3) and 206(a) respectively.

² Entire State of Alaska is included as a CHSDA by regulation (42 CFR 136.22(a)(1)).

³ Aroostook Band of Micmacs was recognized by Congress on November 26, 1991, through the Aroostook Band of Micmac Settlement Act. Aroostook County, ME, was defined as the SDA.

⁴ Special programs have been established by Congress irrespective of the eligibility regulations. Eligibility for services at these facilities is based on the legislative history of the appropriation of funds for the particular facility rather than the eligibility regulations. Historically services have been provided at Brigham City Intermountain School Health Center, Utah (Pub. L. 88–358).

⁵ Entire State of California, excluding the counties of Alameda, Contra Costa, Los Angeles, Marin, Orange, Sacramento, San Francisco, San Mateo, Santa Clara, Kern, Merced, Monterey, Napa, San Benito, San Joaquin, San Luis Obispo, Santa Cruz, Solano, Stanislaus, and Ventura, is designated a CHSDA (25 U.S.C. 1680).

⁶ The counties were recognized after the January 1984 CHSDA FRN was published, in accordance with Public Law 103–116, Catawba Indian Tribe of South Carolina Land Claims Settlement Act of 1993, dated October 27, 1993.

- ⁷ There is no reservation for the Cayuga Nation; the service delivery area consists of those counties identified by the Cayuga Nation.
- ⁸ Skamania County, WA, has historically been a part of the Yakama Service Unit population since 1979.
- ⁹ In order to carry out the Congressional intent of the Siletz Restoration Act, Public Law 95-195, as expressed in H. Report No. 95-623, at page 4, members of the Confederated Tribes of Siletz Indians of Oregon residing in these counties are eligible for contract health services.
- ¹⁰ Chelan County, WA, has historically been a part of the Colville Service Unit population since 1970.
- ¹¹ Pursuant to Public Law 98-481 (H. Rept. No. 98-904), Coos, Lower Umpqua and Siuslaw Restoration Act, members of the Tribe residing in these counties were specified as eligible for Federal services and benefits without regard to the existence of a Federal Indian reservation.
- ¹² The Confederated Tribes of Grand Ronde Community of Oregon were recognized by Public Law 98-165 which was signed into law on November 22, 1983, and provides for eligibility in these six counties without regard to the existence of a reservation.
- ¹³ The CHSDA for the Coushatta Tribe of Louisiana was expanded administratively by the Director, IHS, through regulation (42 CFR 136.22(6)) to include city limits of Elton, LA.
- ¹⁴ Cow Creek Band of Umpqua Tribe of Indians recognized by Public Law 97-391, signed into law on December 29, 1983. House Rept. No. 97-862 designates Douglas, Jackson, and Josephine Counties as a service area without regard to the existence of a reservation. The IHS later administratively expanded the CHSDA to include the counties of Coos, OR, Deschutes, OR, Klamath, OR, and Lane, OR.
- ¹⁵ The Cowlitz Indian Tribe was recognized in July 2002 as documented at 67 FR 46329, July 12, 2002. The counties listed were designated administratively as the SDA, to function as a CHSDA, for the purposes of operating a CHS program pursuant to the ISDEAA, Public Law 93-638. The CHSDA was administratively expanded to include Columbia County, OR, Kittitas, WA, and Wahkiakum County, WA, as published at 67 FR 46329, December 21, 2002.
- ¹⁶ Treasure County, MT, has historically been a part of the Crow Service Unit population.
- ¹⁷ The counties listed have historically been a part of the Grand Traverse Service Unit population since 1980.
- ¹⁸ Haskell Indian Health Center has historically been a part of Kansas Service Unit since 1979. Special programs have been established by Congress irrespective of the eligibility regulations. Eligibility for services at these facilities is based on the legislative history of the appropriation of funds for the particular facility rather than the eligibility regulations. Historically services have been provided at Haskell Indian Health Center (H. Rept. No. 95-392).
- ¹⁹ CHSDA counties for the Ho-Chunk Nation of Wisconsin were designated by regulation (42 CFR 136.22(a)(5)). Dane County, WI, was added to the reservation by the Bureau of Indian Affairs in 1986.
- ²⁰ Public Law 97-428 provides that any member of the Houlton Band of Maliseet Indians in or around the Town of Houlton shall be eligible without regard to existence of a reservation.
- ²¹ The Jena Band of Choctaw Indian was Federally acknowledged as documented at 60 FR 28480, May 31, 1995. The counties listed were designated administratively as the SDA, to function as a CHSDA, for the purposes of operating a CHS program pursuant to the ISDEAA, Public Law 93-638.
- ²² Kickapoo Traditional Tribe of Texas, formerly known as the Texas Band of Kickapoo, was recognized by Public Law 97-429, signed into law on January 8, 1983. The Act provides for eligibility for Kickapoo Tribal members residing in Maverick County without regard to the existence of a reservation.
- ²³ The Klamath Indian Tribe Restoration Act (Pub. L. 99-398, Sec. 2(2)) states that for the purpose of Federal services and benefits "members of the tribe residing in Klamath County shall be deemed to be residing in or near a reservation".
- ²⁴ The Koi Nation of Northern California, formerly known as the Lower Lake Rancheria, was reaffirmed by the Secretary of the Bureau of Indian Affairs on December 29, 2000. The counties listed were designated administratively as the SDA, to function as a PRCDA, for the purposes of operating a PRC program pursuant to the ISDEAA, Public Law 93-638.
- ²⁵ The Little Traverse Bay Bands of Odawa Indians and the Little River Band of Ottawa Indians Act recognized the Little River Band of Ottawa Indians and the Little Traverse Bay Bands of Odawa Indians. Pursuant to Public Law 103-324, Sec. 4 (b) the counties listed were designated administratively as the SDA, to function as a CHSDA, for the purposes of operating a CHS program pursuant to the ISDEAA, Public Law 93-638.
- ²⁶ The Little Traverse Bay Bands of Odawa Indians and the Little River Band of Ottawa Indians Act recognized the Little River Band of Ottawa Indians and the Little Traverse Bay Bands of Odawa Indians. Pursuant to Public Law 103-324, Sec. 4 (b) the counties listed were designated administratively as the SDA, to function as a CHSDA, for the purposes of operating a CHS program pursuant to the ISDEAA, Public Law 93-638.
- ²⁷ Mashantucket Pequot Indian Claims Settlement Act, Public Law 98-134, signed into law on October 18, 1983, provides a reservation for the Mashantucket Pequot Indian Tribe in New London County, CT.
- ²⁸ The Mashpee Wampanoag Tribe was recognized in February 2007, as documented at 72 FR 8007, February 22, 2007. The counties listed were designated administratively as the SDA, to function as a CHSDA, for the purposes of operating a CHS program pursuant to the ISDEAA, Public Law 93-638.
- ²⁹ The Match-e-be-nash-she-wish Band of Pottawatomis Indians of Michigan was recognized in October 1998, as documented at 63 FR 56936, October 23, 1998. The counties listed were designated administratively as the SDA, to function as a CHSDA, for the purposes of operating a CHS program pursuant to the ISDEAA, Public Law 93-638.
- ³⁰ Members of the Mississippi Band of Choctaw Indians residing in Jasper and Noxubee Counties, MS, are eligible for contract health services; these two counties were inadvertently omitted from 42 CFR 136.22.
- ³¹ Members of the Mississippi Band of Choctaw Indians residing in Jasper and Noxubee Counties, MS, are eligible for contract health services; these two counties were inadvertently omitted from 42 CFR 136.22.
- ³² Scott County, MS, has historically been a part of the Choctaw Service Unit population since 1970.
- ³³ The Narragansett Indian Tribe was recognized by Public Law 95-395, signed into law September 30, 1978. Lands in Washington County, RI, are now Federally restricted and the Bureau of Indian Affairs considers them as the Narragansett Indian Reservation.
- ³⁴ Entire State of Nevada is included as a CHSDA by regulation (42 CFR 136.22 (a)(2)).
- ³⁵ Carter County, MT, has historically been a part of the Northern Cheyenne Service Unit population since 1979.
- ³⁶ Land of Box Elder County, Utah, was taken into trust for the Northwestern Band of Shoshoni Nation in 1986.
- ³⁷ The Nottawaseppi Huron Band of the Potawatomi, Michigan, formerly known as the Huron Band of Potawatomi, Inc., was recognized in December 1995, as documented at 60 FR 66315, December 21, 1995. The counties listed were designated administratively as the SDA, to function as a CHSDA, for the purposes of operating a CHS program pursuant to the ISDEAA, Public Law 93-638.
- ³⁸ Washabaugh County, SD, merged and became part of Jackson County, SD, in 1983; both were/are CHSDA counties for the Oglala Sioux Tribe.
- ³⁹ Entire State of Oklahoma is included as a CHSDA by regulation (42 CFR 136.22 (a)(3)).
- ⁴⁰ Paiute Indian Tribe of Utah Restoration Act, Public Law 96-227, provides for the extension of services for the Paiute Indian Tribe of Utah to these four counties without regard to the existence of a reservation.
- ⁴¹ In the FEDERAL REGISTER on July 08, 2015 (80 FR 39144), the Pamunkey Indian Tribe was officially recognized as an Indian Tribe within the meaning of Federal law. The counties listed were designated administratively as the SDA, to function as a CHSDA, for the purposes of operating a CHS program pursuant to the ISDEAA, Public Law 93-638.
- ⁴² Legislative history (H.R. Report No. 95-1021) to Public Law 95-375, Extension of Federal Benefits to Pascua Yaqui Indians, Arizona, expresses congressional intent that lands conveyed to the Pascua Yaqui Tribe of Arizona pursuant to Act of October 8, 1964. (Pub. L. 88-350) shall be deemed a Federal Indian Reservation.
- ⁴³ The Maine Indian Claims Settlement Act of 1980 (Pub. L. 96-420; H. Rept. 96-1353) includes the intent of Congress to fund and provide contract health services to the Passamaquoddy Tribe and the Penobscot Nation.
- ⁴⁴ The Passamaquoddy Tribe has two reservations: Indian Township and Pleasant Point. The PRCDA for the Passamaquoddy Tribe at Indian Township, ME, is Aroostook County, ME, Washington County, ME, and Hancock County, ME. The PRCDA for the Passamaquoddy Tribe at Pleasant Point, ME, is Washington County, ME, south of State Route 9, and Aroostook County, ME.
- ⁴⁵ The Passamaquoddy Tribe's counties listed are designated administratively as the SDA, to function as a PRCDA, for the purposes of operating a PRC program pursuant to the ISDEAA, Public Law 93-638.
- ⁴⁶ The Maine Indian Claims Settlement Act of 1980 (Pub. L. 96-420; H. Rept. 96-1353) includes the intent of Congress to fund and provide PRC to the Passamaquoddy Tribe and the Penobscot Nation.

⁴⁷ Counties in the Service Unit designated by Congress for the Poarch Band of Creek Indians (see H. Rept. 98–886, June 29, 1984; Cong. Record, October 10, 1984, Pg. H11929).

⁴⁸ Public Law 103–323 restored Federal recognition to the Pokagon Band of Potawatomi Indians, Michigan and Indiana, in 1994 and identified counties to serve as the SDA.

⁴⁹ The Ponca Restoration Act, Public Law 101–484, recognized members of the Ponca Tribe of Nebraska in Boyd, Douglas, Knox, Madison or Lancaster counties of Nebraska or Charles Mix county of South Dakota as residing on or near a reservation. Public Law 104–109 made technical corrections to laws relating to Native Americans and added Burt, Hall, Holt, Platte, Sarpy, Stanton, and Wayne counties of Nebraska and Pottawatomie and Woodbury counties of Iowa to the Ponca Tribe of Nebraska SDA.

⁵⁰ Special programs have been established by Congress irrespective of the eligibility regulations. Eligibility for services at these facilities is based on the legislative history of the appropriation of funds for the particular facility, rather than the eligibility regulations. Historically services have been provided at Rapid City (S. Rept. No. 1154, FY 1967 Interior Approp. 89th Cong. 2d Sess.).

⁵¹ Historically part of Isabella Reservation Area for the Saginaw Chippewa Indian Tribe of Michigan and the Eastern Michigan Service Unit population since 1979.

⁵² The Samish Indian Tribe Nation was Federally acknowledged in April 1996 as documented at 61 FR 15825, April 9, 1996. The counties listed were designated administratively as the SDA, to function as a CHSDA, for the purposes of operating a CHS program pursuant to the ISDEAA, Public Law 93–638.

⁵³ CHSDA counties for the Sault Ste. Marie Tribe of Chippewa Indians, Michigan, were designated by regulation (42 CFR 136.22(a)(4)).

⁵⁴ The Shinnecock Indian Nation was Federally acknowledged in June 2010 as documented at 75 FR 34760, June 18, 2010. The counties listed were designated administratively as the SDA, to function as a CHSDA, for the purposes of operating a CHS program pursuant to the ISDEAA, Public Law 93–638.

⁵⁵ Lemhi County, ID, has historically been a part of the Fort Hall Service Unit population since 1979.

⁵⁶ The Snoqualmie Indian Tribe was Federally acknowledged in August 1997 as documented at 62 FR 45864, August 29, 1997. The counties listed were designated administratively as the SDA, to function as a CHSDA, for the purposes of operating a CHS program pursuant to the ISDEAA, Public Law 93–638.

⁵⁷ On December 30, 2011 the Office of Assistant Secretary-Indian Affairs reaffirmed the Federal recognition of the Tejon Indian Tribe. The county listed was designated administratively as the SDA, to function as a CHSDA, for the purposes of operating a CHS program pursuant to the ISDEAA, Public Law 93–638.

⁵⁸ The Secretary acting through the Service is directed to provide contract health services to Turtle Mountain Band of Chippewa Indians that reside in Trenton Service Unit, North Dakota and Montana, in Divide, Mackenzie, and Williams counties in the state of North Dakota and the adjoining counties of Richland, Roosevelt, and Sheridan in the state of Montana (Sec. 815, Pub. L. 94–437).

⁵⁹ Rapides County, LA, has historically been a part of the Tunica Biloxi Service Unit population since 1982.

⁶⁰ According to Public Law 100–95, Sec. 12, members of the Wampanoag Tribe of Gay Head (Aquinnah) residing on Martha's Vineyard are deemed to be living on or near an Indian reservation for the purposes of eligibility for Federal services.

⁶¹ The counties listed are designated administratively as the SDA, to function as a PRCDA, for the purposes of operating a PRC program pursuant to the ISDEAA, Public Law 93–638.

⁶² The Wilton Rancheria, California had Federal recognition restored in July 2009 as documented at 74 FR 33468, July 13, 2009. Sacramento County, CA, was designated administratively as the SDA, to function as a CHSDA. Sacramento County was not covered when Congress originally established the State of California as a CHSDA excluding certain counties including Sacramento County (25 U.S.C. 1680).

⁶³ Public Law 100–89, Restoration Act for Ysleta Del Sur and Alabama and Coshatta Tribes of Texas establishes service areas for “members of the Tribe” by sections 101(3) and 105(a) for the Pueblo and sections 201(3) and 206(a) respectively.

Dated: July 19, 2017.

RADM Michael D. Weahkee,

Assistant Surgeon General, U.S. Public Health Service, Acting Director, Indian Health Service.

[FR Doc. 2017–15963 Filed 7–27–17; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council on Alcohol Abuse and Alcoholism.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections

552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council on Alcohol Abuse and Alcoholism.

Date: September 14, 2017.

Closed: 9:00 a.m. to 9:45 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, Terrace Level Conference Rooms, 5635 Fishers Lane, Rockville, MD 20852.

Open: 10:00 a.m. to 3:15 p.m.

Agenda: Presentations and other business of the council.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, Terrace Level Conference Rooms, 5635 Fishers Lane, Rockville, MD 20852.

Contact Person: Abraham P. Bautista, Ph.D., Executive Secretary, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 5635 Fishers Lane, Room 2085, Rockville, MD 20852, 301–443–9737, bautista@mail.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: https://www.niaaa.nih.gov/news-events/meetings-events-exhibits?field_event_category_tid=16, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards., National Institutes of Health, HHS)

Dated: July 24, 2017.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–15902 Filed 7–27–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****Center for Scientific Review; Amended Notice of Meeting**

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, August 04, 2017, 11:00 a.m. to August 04, 2017, 02:00 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD, 20892 which was published in the **Federal Register** on July 14, 2017, 82 FR 32557.

The meeting will be held on August 03, 2017 at 10:00 a.m. The meeting location remains the same. The meeting is closed to the public.

Dated: July 25, 2017.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017-15953 Filed 7-27-17; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****National Human Genome Research Institute; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Inherited Disease Research Access Committee.

Date: September 8, 2017.

Time: 8:30 a.m. to 11:30 a.m.

Agenda: To review and evaluate grant applications.

Place: Center for Inherited Disease Research, McHenry Room, 5th Floor, 1812 Ashland Avenue Baltimore, MD 21205.

Contact Person: Barbara J. Thomas, Ph.D., Scientific Review Officer, Scientific Review Branch, National Human Genome Research Institute, National Institutes of Health, 5635 Fishers Lane, Ste. 4076, MSC 9306, Bethesda, MD 20892-9306, 301-402-0838, barbara.thomas@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: July 25, 2017.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017-15954 Filed 7-27-17; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID, Clinical Trial Implementation Grant (R01).

Date: August 23, 2017.

Time: 10:00 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Jane K. Battles, Ph.D., Scientific Review Officer Scientific, Review Program Division of Extramural Activities, National Institutes of Health/NIAID, 5601 Fishers Lane, Room 3F30B, Rockville, MD 20852, 240-669-5029, battlesja@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: July 24, 2017.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017-15955 Filed 7-27-17; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Board of Scientific Counselors, NIAAA.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute on Alcohol Abuse and Alcoholism, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIAAA.

Date: October 2, 2017.

Time: 8:30 a.m. to 5:55 p.m.

Agenda: To review and evaluate personal qualifications and performance; and competence of individual investigators.

Place: National Institutes of Health, Building 10, CRC 2-3330, 10 Center Drive, Bethesda, MD 20892.

Contact Person: George Kunos, M.D., Ph.D., Scientific Director, National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 5625 Fishers Lane, Room 2s-24a, Rockville, MD 20852, 301-443-2069, gkunos@mail.nih.gov.

Date: October 3, 2017.

Time: 8:00 a.m. to 5:15 p.m.

Agenda: To review and evaluate personal qualifications and performance; and competence of individual investigators.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, Terrace Level Conference Room, 5635 Fishers Lane, Rockville, MD 20852.

Contact Person: George Kunos, M.D., Ph.D., Scientific Director, National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 5625 Fishers Lane, Room 2s-24a, Rockville, MD 20852, 301-443-2069, gkunos@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards., National Institutes of Health, HHS)

Dated: July 24, 2017.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017-15903 Filed 7-27-17; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request: Specimen Resource Locator (National Cancer Institute)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI) will publish periodic summaries of propose projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit

comments in writing, or request more information on the proposed project, contact: Joanne Demchok, Program Director, Cancer Diagnosis Program, Division of Cancer Treatment and Diagnosis, 9609 Medical Center Drive, Rockville, MD 20892 or call non-toll-free number 240-276-5959 or Email your request, including your address to: peterjo@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) 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) 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 the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Specimen Resource Locator, 0925-0703: Reinstatement without Change, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The availability of specimens and associated data is critical to increase our knowledge of cancer biology, and to translate important research discoveries to clinical application. The discovery and validation of cancer prevention markers require access, by researchers, to quality clinical biospecimens. In response, to this need, the National Cancer Institute's (NCI) Cancer Diagnosis Program has developed, and is expanding, a searchable database: Specimen Resource Locator (SRL). The SRL allows scientist in the research community and the NCI to locate specimens needed for their research. The SRL will list all NCI supported repositories and their links. This administrative submission is an on-line form that will collect information to manage and improve a program and its resources for the use of all scientists. This submission does not involve any analysis.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 105.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Private Sector	Initial Request	70	1	30/60	35
State Government		70	1	30/60	35
Federal Government		60	1	30/60	30
Private Sector	Annual Update	20	1	5/60	2
State Government		20	1	5/60	2
Federal Government		10	1	5/60	1
Total		250	250		105

Dated: July 13, 2017.

Karla Bailey,

Project Clearance Liaison, National Cancer Institute, National Institutes of Health.

[FR Doc. 2017-15952 Filed 7-27-17; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2016-1000]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number: 1625-0025

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an approval for reinstatement, without change, of the following collection of information: 1625-0025, Carriage of Bulk Solids

Requiring Special Handling; without change. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: Comments must reach the Coast Guard and OIRA on or before August 28, 2017.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2016–1000] to the Coast Guard using the Federal eRulemaking Portal at <http://www.regulations.gov>. Alternatively, you may submit comments to OIRA using one of the following means:

(1) Email: dhsdeskofficer@omb.eop.gov.

(2) Mail: OIRA, 725 17th Street NW., Washington, DC 20503, attention Desk Officer for the Coast Guard.

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. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, [USCG–2016–1000], and must be received by August 28, 2017.

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 Web site'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).

OIRA posts its decisions on ICRs online at <http://www.reginfo.gov/public/do/PRAMain> after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Number: 1625–0025.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard has published the 60-day notice (81 FR 95625, December 28, 2016) required by 44 U.S.C. 3506(c)(2). That Notice elicited no comments. Accordingly, no changes have been made to the Collections.

Information Collection Request

Title: Carriage of Bulk Solids Requiring Special Handling—46 CFR part 148.

OMB Control Number: 1625–0025.

Summary: As specified in 46 CFR part 148, the petition for a Special Permit allows the Coast Guard to determine the

manner of safe carriage for unlisted materials. The information required by Dangerous Cargo Manifests and Shipping Papers permit vessel crews and emergency personnel to properly and safely respond to accidents involving hazardous substances. See 46 CFR 148 Subpart B and 148.60 and 148.70.

Need: The Coast Guard administers and enforces statutes and rules for the safe transport and stowage of hazardous materials, including solids.

Forms: None.

Respondents: Owners and operators of vessels that carry certain bulk solids.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has decreased from 955 hours to 850 hours a year due to a decrease in the estimated annual number of responses for Special Permits.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: July 18, 2017.

Marilyn Scott-Perez,

U.S. Coast Guard, Chief, Office of Information Management.

[FR Doc. 2017–15870 Filed 7–27–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNM950000 L14400000.BJ0000
LXSSG0200000 17X]

Notice of Filing of Plat of Survey; Oklahoma, Suspended

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of official filing.

On Friday, June 12, 2009, there was published in the **Federal Register**, Volume 74, Number 112, on pages 28061 and 28062, a notice entitled, “Notice of Filing of Plats of Survey, New Mexico, Oklahoma, Texas, and Kansas.” Said Notice referenced the filing of the plat of Townships 5 and 6 South, Range 12 West of the Indian Meridian, Oklahoma, accepted May 8, 2009, for Group 85 OK. This plat officially filed on July 13, 2009, is hereby suspended to allow for investigation of the survey methodology used to identify the gradient boundary. On Thursday, February 25, 2010, there was published in the **Federal Register**, Volume 75, Number 37, on pages 8738 and 8739, a Notice entitled, “Notice of Filing of Plats of Survey, NM.” Said Notice referenced a filing of the plats of Township 5 South, Range 13 West, of the Indian Meridian—Oklahoma,

accepted September 24, 2009, for group 80 OK; and Township 5 South Range 15 West, of the Indian Meridian—Oklahoma, accepted September 24, 2009, for Group 82 OK. Both were officially filed on July 19, 2010.

Both plats are hereby suspended to allow for investigation of the survey methodology used to identify the gradient boundary.

As explained by the Glossaries of BLM Surveying and Mapping Terms (2nd ed.), the BLM may suspend a plat of survey when a question or doubt arises concerning its correctness. Once suspended, the BLM may correct, reinstate, or cancel the survey, either in whole or in part; however, the BLM may not initiate or complete an action based on the survey while it is suspended.

Amy Lueders,
State Director.

[FR Doc. 2017-15957 Filed 7-27-17; 8:45 am]

BILLING CODE 4310-FB-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLWYP00000-L51100000-GA0000-LVEMK16CY810 17X; WYW184599]

Notice of Intent To Prepare an Environmental Impact Statement and Notice of Public Meeting on a Federal Coal Lease-by-Application in the Decertified Powder River Federal Coal Production Region, Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of intent and notice of public meeting.

SUMMARY: Pursuant to the National Environmental Policy Act of 1969 (NEPA), as amended, the Bureau of Land Management (BLM), High Plains District Office announces its intent to prepare an Environmental Impact Statement (EIS) on the potential impacts of leasing a tract of Federal coal. The EIS will be called the West Antelope 3 Coal Lease by Application EIS. Antelope Coal, LLC (Antelope) applied for a coal lease for approximately 3,508.31 acres (containing approximately 441 million tons of in-place coal) in a maintenance tract of Federal coal adjacent to the Antelope Mine in Campbell and Converse Counties, Wyoming.

DATES: Comments may be submitted in writing until September 26, 2017. The BLM will host a public scoping meeting on September 20, 2017, at 7 p.m. to provide the public with an opportunity to review the proposal and gain an understanding of the coal leasing process.

ADDRESSES: Please submit written comments or concerns to the BLM High Plains District Office, Attn: Teresa Johnson, 2987 Prospector Drive, Casper, Wyoming 82604.

Written comments or resource information may also be hand-delivered to the BLM High Plains District Office, or sent by facsimile to the attention of Teresa Johnson at (307) 261-7587. Comments may be sent electronically to blm_wy_west_antelope_3@blm.gov. Please put "West Antelope 3 Coal EIS Scoping Comment" in the subject line.

The September 20 public scoping meeting will be held at the Wright Community Center, 201 Wright Blvd., Wright, Wyoming.

The BLM will announce future public meetings and other opportunities to submit comments on this project at least 15 days prior to the event through local news media and the BLM Wyoming Coal ePlanning Public Interface Site at: <http://bit.ly/PRBcoal>. Project information is available at the West Antelope 3 Web site located at: <http://bit.ly/WestAntelope3>.

Members of the public may examine documents pertinent to this proposal by visiting the BLM High Plains District Office during its business hours (7:45 a.m. to 4:30 p.m.), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Teresa Johnson or Steve Wright, BLM High Plains District Office, 2987 Prospector Drive, Casper, Wyoming 82604. Ms. Johnson or Mr. Wright may also be reached at (307) 261-7600. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at (800) 877-8339 to contact Ms. Johnson or Mr. Wright during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individuals. You will receive a reply during normal business hours. You may call either of these numbers to have your name added to the project mailing list.

SUPPLEMENTARY INFORMATION: Antelope Coal, LLC submitted an application on August 24, 2015, to lease a maintenance tract of Federal coal adjacent to the company's Antelope Mine in Campbell and Converse Counties, Wyoming. A maintenance tract is a parcel of land containing Federal coal reserves that can be leased to maintain production at an existing mine. The tract, referred to as the West Antelope 3 Tract, has been assigned case number WYW-184599.

The West Antelope 3 Tract includes approximately 441 million tons of in-place Federal coal underlying the

following lands in Campbell and Converse Counties, Wyoming:

Sixth Principal Meridian, Wyoming

T. 41 N., R. 71 W.,
Sec. 8;
Sec. 9, lots 1 thru 8;
Sec. 10, lot 5;
Secs. 17 and 19;
Sec. 20, lots 1 thru 13;
Sec. 29, lots 4, 5, 12, and 13;
Sec. 30, lots 5 thru 16.
Containing 3,508.31 acres.

Antelope Coal proposes to mine the tract as a part of the Antelope Mine. At the 2015 mining rate of approximately 35.2 million tons per year, the coal included in the West Antelope 3 Tract would extend the life of the Antelope Mine by as many as 10 years. Lands in the West Antelope 3 Tract contain private surface estate overlying the Federal coal. The Antelope Mine is operating under approved mining permits from the Land Quality and Air Quality Divisions of the Wyoming Department of Environmental Quality.

Consistent with Federal regulations under NEPA and the Mineral Leasing Act of 1920 (MLA), as amended, the BLM must prepare an environmental analysis prior to holding a competitive Federal coal lease sale. The Powder River Regional Coal Team recommended that the BLM process this coal lease application after they reviewed the West Antelope 3 Tract at a public meeting held on January 27, 2016, in Casper, Wyoming.

The Office of Surface Mining Reclamation and Enforcement (OSMRE) will be a cooperating agency in the preparation of the EIS. If the tract is leased to the applicant, the new lease must be incorporated into the existing mining and reclamation plans for the adjacent mine. Before the Federal coal in the tract can be mined, the Assistant Secretary for Land and Minerals Management must approve the revised mining plan for the mine in which the tract will be included. The OSMRE is the Federal agency that is responsible for recommending approval, approval with conditions, or disapproval of the revised mining plan to the Assistant Secretary for Land and Minerals Management. Other cooperating agencies may be identified during the scoping process.

The BLM will provide interested parties the opportunity to submit comments relating to the scope of the EIS or relevant information or both. This information will help the BLM identify issues to be considered in preparing the West Antelope 3 Coal Lease by Application EIS. Issues that have been identified in analyzing the impacts of

previous Federal coal leasing actions in the Wyoming Powder River Basin (PRB) include: The need for resolution of conflicts between existing and proposed oil and gas development and coal mining on the tracts proposed for coal leasing; potential impacts to big-game herds and hunting; potential impacts to sage grouse; potential impacts to listed threatened and endangered species; potential health impacts related to blasting operations conducted by the mines to remove overburden and coal; the need to consider the cumulative impacts of coal leasing decisions combined with other existing and proposed development in the Wyoming PRB; potential impacts to climate change through greenhouse gas emissions; and potential site-specific and cumulative impacts on air and water quality.

Public response is important, and will be considered in the EIS process. At the scoping meeting, the public is invited to submit comments and resource information, and identify issues or concerns to be considered in the NEPA analysis for the coal leasing process.

The BLM can best use public input if written comments and resource information are submitted by the end of the 60-day scoping period. Please note that comments and information submitted regarding this project, including names, electronic mail addresses and street addresses of the respondents, will be available for public review and disclosure at the BLM High Plains District Office, and may be published in the West Antelope 3 Coal Lease by Application EIS.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 40 CFR 1501.7 and 1506.6, and 43 CFR 3425.3.

Mary Jo Rugwell,

Wyoming State Director, Bureau of Land Management.

[FR Doc. 2017–15856 Filed 7–27–17; 8:45 am]

BILLING CODE 4310–22–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–17–032]

Government in the Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: United States International Trade Commission.

DATE AND TIME: August 4, 2017 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 in Inv. Nos. 701–TA–582 and 731–TA–1377 (Preliminary) (Ripe Olives from Spain). The Commission is currently scheduled to complete and file its determinations on August 7, 2017; views of the Commission are currently scheduled to be completed and filed on August 14, 2017
 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.

By order of the Commission.

Issued: July 25, 2017.

William R. Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2017–16031 Filed 7–26–17; 11:15 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–410 (Fourth Review)]

Light-Walled Rectangular Pipe and Tube From Taiwan; Determination

On the basis of the record¹ developed in the subject five-year review, the United States International Trade Commission (“Commission”) determines, pursuant to the Tariff Act of 1930 (“the Act”), that revocation of the antidumping duty order on light-walled rectangular pipe and tube from Taiwan would be likely to lead to continuation or recurrence of material injury to an

industry in the United States within a reasonably foreseeable time.

Background

The Commission, pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)), instituted this review on January 3, 2017 (82 FR 137) and determined on April 10, 2017 that it would conduct an expedited review (82 FR 21406, May 8, 2017).

The Commission made this determination pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)). It completed and filed its determination in this review on July 25, 2017. The views of the Commission are contained in USITC Publication 4707 (July 2017), entitled *Light-Walled Rectangular Pipe and Tube from Taiwan: Investigation No. 701–TA 410 (Fourth Review)*.

By order of the Commission.

Issued: July 25, 2017.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2017–15936 Filed 7–27–17; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–17–031]

Government in the Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: United States International Trade Commission.

DATE AND TIME: August 3, 2017 at 9:30 a.m.

PLACE: 500 E Street SW., Room 101, 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 in Inv. Nos. 731–TA–1334–1337 (Final)(Emulsion Styrene-Butadiene Rubber from Brazil, Korea, Mexico, and Poland). The Commission is currently scheduled to complete and file its determinations and views of the Commission by August 23, 2017.
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.

By order of the Commission.

¹ The record is defined in sec. 207.2(f) of the Commission’s Rules of Practice and Procedure (19 CFR 207.2(f)).

Issued: July 25, 2017.

William R. Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2017-16032 Filed 7-26-17; 11:15 am]

BILLING CODE 7020-02-P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140-0019]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Federal Firearms License (FFL) RENEWAL Application—ATF F 8 (5310.11) Part 11

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice

ACTION: 30-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 information collection was previously published in the [Federal Register, on May 25, 2017, allowing for a 60-day comment period].

DATES: Comments are encouraged and will be accepted for an additional 30 days until August 28, 2017.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, particularly with respect to the estimated public burden or associated response time, have suggestions, need a copy of the proposed information collection instrument with instructions, or desire any other additional information, please contact Tracey Robertson, Chief, Federal Firearms Licensing Center either by mail at 244 Needy Road, Martinsburg, WV 20226, by email at Tracey.Robertson@atf.gov. Written comments and/or suggestions can also be directed 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 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:* Extension, without change, of a currently approved collection.

(2) *The Title of the Form/Collection:* Federal Firearms License (FFL) RENEWAL Application.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

(4) *Form number:* ATF F 8 (5310.11) Part 11.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

(5) *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Business or other for-profit.

Other: Individuals or households.

Abstract: The form is filed by the licensee desiring to renew a Federal firearms license. It is used to identify the applicant, locate the business/collection premises, identify the type of business/collection activity, and determine the eligibility of the applicant.

(6) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 35,000 respondents will utilize the form, and it will take each respondent 30 minutes to complete the form.

(7) *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 17,500 hours which is equal to (35,000 (total # of respondents * .5(30 minutes).

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: July 25, 2017.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2017-15925 Filed 7-27-17; 8:45 am]

BILLING CODE 4410-14-P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (17-052)]

Notice of Intent To Grant Partially Exclusive Term License

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of intent to grant partially exclusive patent license.

SUMMARY: NASA hereby gives notice of its intent to grant a partially exclusive patent license in the United States to practice the invention described and claimed in U.S. Patent 8,813,577 entitled “Self-Contained Compressed-Flow Generation Device for use in making Differential Measurements,” U.S. Patent 8,555,731 entitled “Self-Contained Compressed-Flow Generation Device for use in making Differential Measurements,” U.S. Patent 8,739,638 entitled “Star-Shaped fluid flow tool for use in making differential measurements,” and U.S. Patent 8,733,180 entitled “Airfoil-shaped Fluid Flow Tool for use in making Differential Measurements,” to AquaStar Pool Products, Inc., having its principal place of business in Ventura, California. The fields of use may be limited to pool products and supplies. NASA has not yet made a determination to grant the requested license and may deny the requested license even if no objections are submitted within the comment period.

DATES: The prospective partially exclusive license may be granted unless NASA receives written objections, including evidence and argument, no later than August 14, 2017 that establish that the grant of the license would not be consistent with the requirements regarding the licensing of federally owned inventions as set forth in the Bayh-Dole Act and implementing regulations. Competing applications completed and received by NASA no later than August 14, 2017 will also be treated as objections to the grant of the contemplated exclusive license.

Objections submitted in response to this notice will not be made available to the public for inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act.

ADDRESSES: Objections relating to the prospective license may be submitted to Mr. James J. McGroary, Chief Patent Counsel/LS01, Marshall Space Flight Center, Huntsville, Alabama 35812, (256) 544-0013.

FOR FURTHER INFORMATION CONTACT: Mr. Sammy A. Nabors, Technology Transfer Branch (ST22), Marshall Space Flight Center, Huntsville, Alabama 35812, (256) 544-5226.

SUPPLEMENTARY INFORMATION: This notice of intent to grant an exclusive patent license is issued in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i). The patent rights in these inventions have been assigned to the United States of America as represented by the Administrator of the National Aeronautics and Space Administration. The prospective partially exclusive license will comply with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Information about other NASA inventions available for licensing can be found online at <http://technology.nasa.gov>.

Mark P. Dvorscak,

Agency Counsel for Intellectual Property.

[FR Doc. 2017-15291 Filed 7-27-17; 8:45 am]

BILLING CODE 7510-13-P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[NOTICE: (17-054)]

Notice of Information Collection

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of information collection.

SUMMARY: The National Aeronautics and Space Administration, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections.

DATES: All comments should be submitted within 30 calendar days from the date of this publication.

ADDRESSES: Interested persons are invited to submit written comments regarding the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 7th Street NW., Washington, DC 20543. Attention: Desk Officer for NASA.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Frances Teel, NASA Clearance Officer, NASA Headquarters, 300 E Street SW., JF0000, Washington, DC 20546, (202) 358-2225.

SUPPLEMENTARY INFORMATION:

I. Abstract

Homeland Security Presidential Directive 12 (HSPD-12) established a mandatory requirement for a Government-wide identify verification standard. In compliance with HSPD-12 and the National Institute of Standards and Technology (NIST) Federal Information Processing Standard (FIPS) 201: Personal Identity Verification of Federal Employees and Contractors, and OMB Policy memorandum M-05-24 Implementation of Homeland Security Presidential Directive 12, NASA must collect information from members of the public to: (1) Validate identity and (2) issue secure and reliable federal credentials to enable access to NASA facilities/sites and NASA information systems. Information collected is consistent with background investigation data to include but not limited to name, date of birth, citizenship, social security number (SSN), address, employment history, biometric identifiers (e.g. fingerprints), signature, digital photograph.

NASA collects information from U.S. Citizens requiring access 30 or more days in a calendar year. NASA also collects information from foreign nationals regardless of their affiliation time.

NASA collects, stores, and secures information from individuals identified above in the NASA Identify Management System (IdMAX) in a manner consistent with the Constitution and applicable laws, including the Privacy Act (5 U.S.C. 552a.)

Information is collected via a combination of electronic and paper processes and stored in the NASA Identify Account Exchange (IdMAX) System.

II. Method of Collection

Electronic (90%) and paper (10%).

III. Data

Title: Personal Identity Validation for Routine and Intermittent Access to NASA Facilities, Sites, and Information Systems.

OMB Number: 2700-0158.

Type of review: Extension without change of a currently approved information collection.

Affected Public: Individuals.

Estimated Number of Respondents: 52,000.

Estimated Time Per Response: 10 minutes.

Estimated Total Annual Public Burden Hours: 8,667.

Estimated Total Annual Government Cost: \$1,189,350.00.

IV. Request for Comments

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of NASA, including whether the information collected has practical utility; (2) the accuracy of NASA's estimate of the burden (including hours and cost) of the proposed collection of information; (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 automated collection techniques or the use of other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of this information collection. They will also become a matter of public record.

Frances Teel,

NASA PRA Clearance Officer.

[FR Doc. 2017-15938 Filed 7-27-17; 8:45 am]

BILLING CODE 7510-13-P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Federal Council on the Arts and the Humanities; Arts and Artifacts Indemnity Panel Advisory Committee

AGENCY: National Foundation on the Arts and the Humanities.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, notice is hereby given that the Federal Council on the Arts and the Humanities will hold a meeting of the Arts and Artifacts International Indemnity Panel.

DATES: The meeting will be held on Monday, August 21, 2017, from 12:00 p.m. to 5:00 p.m.

ADDRESSES: The meeting will be held by teleconference originating at the National Endowment for the Arts, Washington, DC 20506.

FOR FURTHER INFORMATION CONTACT: Elizabeth Voyatzis, Committee Management Officer, 400 7th Street SW., Room 4060, Washington, DC 20506, (202) 606 8322; evoyatzis@neh.gov.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is for panel review, discussion, evaluation, and recommendation on applications for Certificates of Indemnity submitted to the Federal Council on the Arts and the Humanities, for exhibitions beginning before, on, or after October 1, 2017. Because the meeting will consider proprietary financial and commercial data provided in confidence by indemnity applicants, and material that is likely to disclose trade secrets or other privileged or confidential information, and because it is important to keep the values of objects to be indemnified, and the methods of transportation and security measures confidential, I have determined that that the meeting will be closed to the public pursuant to subsection (c)(4) of section 552b of Title 5, United States Code. I have made this determination under the authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee Meetings, dated April 15, 2016.

Dated: July 25, 2017.

Elizabeth Voyatzis,
Committee Management Officer.

[FR Doc. 2017-15928 Filed 7-27-17; 8:45 am]

BILLING CODE 7536-01-P

POSTAL REGULATORY COMMISSION

[Docket No. CP2017-224]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning negotiated service agreements. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* August 1, 2017.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at <http://www.prc.gov>. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202-789-6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's Web site (<http://www.prc.gov>). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3007.40.

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3010, and 39 CFR part 3020, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s):* CP2017-224; *Filing Title:* Notice of United States Postal Service of Filing a Functionally Equivalent Global Reseller Expedited Package 2 Negotiated Service Agreement; *Filing Acceptance Date:* July 24, 2017; *Filing Authority:* 39 CFR 3015.5; *Public Representative:* Gregory Stanton; *Comments Due:* August 1, 2017.

This notice will be published in the **Federal Register**.

Stacy L. Ruble,
Secretary.

[FR Doc. 2017-15937 Filed 7-27-17; 8:45 am]

BILLING CODE 7710-FW-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-81194; File Nos. SR-DTC-2017-004; SR-NSCC-2017-005; SR-FICC-2017-008]

Self-Regulatory Organizations; The Depository Trust Company; National Securities Clearing Corporation; Fixed Income Clearing Corporation; Notice of Filing Amendment No. 2, Notice of Filing Amendment No. 3, and Order Instituting Proceedings To Determine Whether To Approve or Disapprove Proposed Rule Changes, as Previously Modified by Amendment No. 1, To Adopt the Clearing Agency Liquidity Risk Management Framework

July 24, 2017.

I. Introduction

On April 6, 2017, The Depository Trust Company ("DTC"), National Securities Clearing Corporation ("NSCC"), and Fixed Income Clearing Corporation ("FICC," each a "Clearing Agency," and collectively, the "Clearing Agencies"), filed with the Securities and Exchange Commission ("Commission") proposed rule changes SR-DTC-2017-004, SR-NSCC-2017-005, and SR-FICC-2017-008, respectively, pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder.² On April 13, 2017, the Clearing Agencies each filed Amendment No. 1 to their respective proposed rule changes. Amendment No. 1 made technical corrections to each Exhibit 5 of the proposed rule change filings. The proposed rule changes, as modified in each instance by Amendment No. 1, were published for comment in the **Federal Register** on April 25, 2017.³ On June 7, 2017, the Commission designated a longer period for Commission Action on the proposed rule changes, as amended in each instance by Amendment No. 1.⁴ As of

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ Securities Exchange Act Release No. 80489 (April 19, 2017), 82 FR 19120 (April 25, 2017) (SR-DTC-2017-004, SR-NSCC-2017-005, SR-FICC-2017-008) ("Notice").

⁴ Securities Exchange Act Release No. 80877 (June 7, 2017), 82 FR 27094 (June 13, 2017) (SR-DTC-2017-004, SR-NSCC-2017-005, SR-FICC-2017-008).

July 20, 2017, the Commission did not receive any comment letters on the proposed rule changes, as amended.

On July 20, 2017, the Clearing Agencies each filed Amendment No. 2 to their respective proposed rule changes, as previously modified by Amendment No. 1. On July 21, 2017, the Clearing Agencies each filed Amendment No. 3 to their respective proposed rule changes to supersede and replace Amendment No. 2 in its entirety, due to a technical defect of Amendment No. 2. Pursuant to Section 19(b)(1) of the Exchange Act⁵ and Rule 19b-4 thereunder,⁶ notice is hereby given that the Commission is publishing this notice to solicit comments on the proposed rule changes, as modified by Amendment No. 3, from interested persons (hereinafter, “Proposed Rule Changes.”). Additionally, this order institutes proceedings under Section 19(b)(2)(B) of the Act⁷ to determine whether to approve or disapprove the Proposed Rule Changes.

II. Description of the Proposed Rule Changes

The Clearing Agencies propose to adopt the Clearing Agency Liquidity Risk Management Framework (“Framework”) of the Clearing Agencies, which would set forth the Clearing Agencies’ (A) liquidity resources, and (B) liquidity risk management practices, to include measurement and monitoring of their respective liquidity risks.⁸ More specifically, the Framework would describe FICC and NSCC’s liquidity risk management strategy and objectives, which are to maintain sufficient liquid resources in order to meet the potential amount of funding required to settle outstanding transactions of a defaulting Member, or affiliated family (“Affiliated Family”) of Members, in a timely manner.⁹ For DTC, the Framework would describe how DTC’s liquidity management strategy and controls are designed to maintain sufficient available liquid resources to complete system-wide settlement on each business day with a high degree of confidence notwithstanding the failure to settle of a Participant or Affiliated Family of Participants.¹⁰ The Framework would

also state that DTC operates on a fully collateralized basis.¹¹

In addition, the Framework would outline the regulatory requirements that would be applicable to each Clearing Agency with respect to liquidity risk management.¹² The Framework would be owned and managed by the Liquidity Product Risk Unit (“LPRU”) of DTCC.¹³ Although the Clearing Agencies would consider the Framework to be a rule of each Clearing Agency, the Proposed Rule Changes do not require any changes to the Rules, By-laws and Organization Certificate of DTC (“DTC Rules”), the Rulebook of GSD (“GSD Rules”), the Clearing Rules of MBSD (“MBSD Rules”), or the Rules & Procedures of NSCC (“NSCC Rules”), as the Framework would be a standalone document.¹⁴

The Clearing Agencies each filed Amendment No. 3 to the proposed rule changes, as previously modified, in order to clarify the three types of scenarios used in daily liquidity sufficiency testing to measure each Clearing Agency’s available liquidity resources, as described below.

A. Liquidity Resources

The Framework would address how each of the Clearing Agencies meets its requirement to hold qualifying liquid resources, as defined by Rule 17Ad-22(a)(14) under the Act,¹⁵ sufficient to meet its minimum liquidity resource requirement in each relevant currency for which it has payment obligations owed to its Members or Participants, as applicable.¹⁶ The Framework also would identify each of the qualifying liquid resources available to each Clearing Agency. Such qualifying liquid resources include, for example, (1) deposits to the Clearing Agencies’ respective Clearing Funds, or, for DTC, its Participants Fund, made by Members or Participants pursuant to the respective rules;¹⁷ (2) for DTC and

NSCC, an annual committed credit facility;¹⁸ (3) for NSCC, its Members’ Supplemental Liquidity Deposits;¹⁹ and (4) for GSD and MBSD, a rule-based Capped Contingency Liquidity Facility (“CCLF”) program.²⁰ The Framework also would state that the Clearing Agencies may have access to other available liquidity resources that may not meet the definition of qualifying liquid resources.²¹

B. Liquidity Measurement and Monitoring

The Framework would describe the manner in which FICC and NSCC measure and monitor the sufficiency of their respective qualifying liquid resources to meet the cash settlement obligations of their respective largest Affiliated Family, through daily liquidity studies, across a range of stress scenarios.²² The Framework would state that FICC and NSCC would perform daily liquidity sufficiency testing using three types of scenarios: (1) Normal market scenarios, as a baseline reference point to assess other stress assumptions;²³ (2) scenarios designed to meet the requirements set forth in Rule 17Ad-22(e)(7)(i);²⁴ and (3) scenarios designed to meet the requirements set forth in Rule 17Ad-22(e)(7)(vi).²⁵ The Framework would describe the manner in which scenarios reflecting these three sets of conditions are developed and selected for testing.²⁶ The Framework would also describe how the summary results of certain scenario analyses are escalated to Clearing Agency management on at least a monthly basis, and how these results are used to evaluate the adequacy of the liquidity resources of FICC or NSCC.²⁷

¹⁸ See Securities Exchange Act Release No. 77750 (April 29, 2016), 81 FR 27181 (May 5, 2016) (SR-DTC-2016-801, SR-NSCC-2016-801). Notice, 82 at 19121.

¹⁹ NSCC Rule 4A (Supplemental Liquidity Deposits). *Supra* note 8. Notice, 82 at 19121.

²⁰ MBSD Rule 17, Section 2a (Procedures for When the Corporation Ceases to Act). *Supra* note 8. GSD has filed a proposed rule change and related advance notice to adopt a CCLF program. See Securities Exchange Act Release No. 80234 (March 14, 2017), 82 FR 14401 (March 20, 2017) (SR-FICC-2017-002). The Notice of No Objection to Advance Notice Filing to Implement the Capped Contingency Liquidity Facility in the Government Securities Division Rulebook was issued. Securities Exchange Act Release No. 81054 (June 29, 2017), 82 FR 13876 (March 15, 2017) (SR-FICC-2017-802). Upon Commission approval of this proposed rule change, GSD’s CCLF program will become a qualifying liquid resource of GSD. Notice, 82 at 19121.

²¹ Notice, 82 at 19121.

²² *Id.*

²³ *Id.*

²⁴ 17 CFR 240.17Ad-22(e)(7)(i).

²⁵ 17 CFR 240.17Ad-22(e)(7)(vi).

²⁶ Notice, 82 at 19121.

²⁷ *Id.*

¹¹ *Id.*

¹² *Id.*

¹³ The parent company of the Clearing Agencies is The Depository Trust & Clearing Corporation (“DTCC”). DTCC operates on a shared services model with respect to the Clearing Agencies. Most corporate functions are established and managed on an enterprise-wide basis pursuant to intercompany agreements under which it is generally DTCC that provides a relevant service to a Clearing Agency. *Id.*

¹⁴ Available at <http://www.dtcc.com/en/legal/rules-and-procedures>. FICC is comprised of two divisions: The Government Securities Division (“GSD”) and the Mortgage-Backed Securities Division (“MBSD”). Notice, 82 at 19120.

¹⁵ 17 CFR 240.17Ad-22(a)(14).

¹⁶ Notice, 82 at 19121.

¹⁷ DTC Rule 4 (Participants Fund and Participants Investment), GSD Rule 4 (Clearing Fund and Loss Allocation), MBSD Rule 4 (Clearing Fund and Loss Allocation), NSCC Rule 4 (Clearing Fund). *Supra* note 8. Notice, 82 at 19121.

⁵ 15 U.S.C. 78s(b)(1).

⁶ 17 CFR 240.19b-4.

⁷ 15 U.S.C. 78s(b)(2)(B).

⁸ Notice, 82 at 19120–19121.

⁹ FICC and NSCC refer to their participants as “Members,” while DTC refers to its participants as “Participants.” These terms are defined in the rules of each of the Clearing Agencies. *Supra* note 4. Notice, 82 at 19121.

¹⁰ Notice, 82 at 19121.

With respect to DTC's measurement of the sufficiency of its liquidity resources, the Framework would set forth that DTC's risk management tools, including the Collateral Monitor and Net Debit Cap,²⁸ limit DTC's liquidity exposure and, thus, DTC's liquidity requirement in default scenarios.²⁹ The Framework would describe how these risk management tools enable DTC to regularly test the sufficiency of its liquid resources on an intraday and end-of-day basis and adjust to stressed circumstances during a settlement day to protect DTC and its Participants against liquidity exposure under normal and stressed market conditions.³⁰

The Framework would describe how the Clearing Agencies review the limits of outstanding investments and collateral held (if applicable) of each Clearing Agency's investment counterparties, and conduct formal reviews of the reliability of their qualified liquidity providers in extreme but plausible market conditions.³¹ The Framework would further describe how the Clearing Agencies undertake due diligence with respect to their liquidity providers, and how NSCC and DTC conduct operational testing with their committed credit facility lenders at least annually.³²

The Framework would describe how the Clearing Agencies would address foreseeable liquidity shortfalls that would not be covered by their existing liquid resources, and would describe how their existing qualified liquid resources may be replenished.³³ The Framework would state that the Clearing Agencies' liquidity risk models are subject to independent model validation on at least an annual basis.³⁴ The Framework would describe the manner in which Clearing Agency liquidity risks are assessed and escalated through liquidity risk management controls that include a statement of risk tolerances that are specific to liquidity risk ("Liquidity Risk Tolerance Statement"), and an operational risk profile of LPRU, which contains consolidated risk and control data.³⁵ Finally, the Framework would state that the Liquidity Risk Tolerance Statement is reviewed by management

within the LPRU annually, and is escalated to the Risk Committee of the Boards for review and approval at least annually.³⁶

III. Proceedings To Determine Whether To Approve or Disapprove the Proposed Rule Changes and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act,³⁷ to determine whether the Proposed Rule Changes should be approved or disapproved. Institution of such proceedings is appropriate at this time in view of the legal and policy issues raised by the Proposed Rule Changes. As noted above, institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, the Commission seeks and encourages interested persons to comment on the Proposed Rule Changes, and provide arguments to support the Commission's analysis as to whether to approve or disapprove the Proposed Rule Changes.

Pursuant to Section 19(b)(2)(B) of the Act,³⁸ the Commission is providing notice of the grounds for disapproval under consideration. The Commission is instituting proceedings to allow for additional analysis of, and input from commenters with respect to, the Proposed Rule Changes' consistency with the Act and the rules thereunder. Specifically, the Commission believes that the Proposed Rule Changes raise questions as to whether they are consistent with (i) Section 17A(b)(3)(F) of the Act,³⁹ which requires, in part, that the rules of the Clearing Agencies be designed to promote the prompt and accurate clearance and settlement of securities transactions, and to assure the safeguarding of securities and funds which are in the custody or control of the Clearing Agencies or for which they are responsible, and (ii) Rule 17Ad-22(e)(7) under the Act, which requires, in general, that each covered clearing agency establish, implement, maintain and enforce written policies and procedures reasonably designed to, among other things effectively measure, monitor, and manage the liquidity risks that arise in or are borne by the covered clearing agency, including measuring, monitoring, and managing its settlement and funding flows on an ongoing and timely basis, and its use of intraday liquidity.⁴⁰

IV. Request for Written Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to the Proposed Rule Changes. In particular, the Commission invites the written views of interested persons concerning whether the Proposed Rule Changes are consistent with Section 17A(b)(3)(F) of the Act,⁴¹ Rule 17Ad-22(e)(7) under the Act,⁴² or any other provision of the Act, rules, and regulations thereunder.

Interested persons are invited to submit written data, views, and arguments regarding whether the Proposed Rule Changes should be approved or disapproved on or before August 18, 2017. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal on or before September 1, 2017. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-DTC-2017-004, SR-NSCC-2017-005, or SR-FICC-2017-008 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549.

All submissions should refer to File Number SR-DTC-2017-004, SR-NSCC-2017-005, or SR-FICC-2017-008. One of these file numbers should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the Proposed Rule Changes that are filed with the Commission, and all written communications relating to the Proposed Rule Changes between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official

²⁸ "Collateral Monitor" and "Net Debit Cap" are defined in DTC Rule 1, Section 1 (Definitions), and their calculations are further provided for in the DTC Settlement Service Guide of the DTC Rules. *Supra* note 8.

²⁹ Notice, 82 at 19121.

³⁰ *Id.*

³¹ *Id.*

³² *Id.*

³³ *Id.*

³⁴ *Id.*

³⁵ Notice, 82 at 19121–19122.

³⁶ Notice, 82 at 19122.

³⁷ 15 U.S.C. 78s(b)(2)(B).

³⁸ *Id.*

³⁹ 15 U.S.C. 78q-1(b)(3)(F).

⁴⁰ 17 CFR 240.17Ad-22(e)(7).

⁴¹ 15 U.S.C. 78q-1(b)(3)(F).

⁴² 17 CFR 240.17Ad-22(e)(7).

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 Clearing Agencies, and on DTCC's Web site (<http://dtcc.com/legal/sec-rule-filings.aspx>). All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR-DTC-2017-004, SR-NSCC-2017-005, or SR-FICC-2017-008 and should be submitted on or before August 18, 2017. If comments are received, any rebuttal comments should be submitted on or before September 1, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁴³

Eduardo A. Aleman,
Assistant Secretary.

[FR Doc. 2017-15907 Filed 7-27-17; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-81197; File No. SR-NYSEArca-2017-46]

Self-Regulatory Organizations; NYSE Arca, Inc.; Order Approving a Proposed Rule Change To Amend NYSE Arca Equities Rule 13.2, Liability of Corporation

July 24, 2017.

I. Introduction

On May 23, 2017, NYSE Arca, Inc. ("NYSE Arca" 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 amend NYSE Arca Equities Rule 13.2, Liability of Corporation. The proposed rule change was published for comment in the **Federal Register** on June 12, 2017.³ The Commission received no comments on the proposed rule change. This order approves the proposed rule change.

II. Description of the Proposed Rule Change⁴

NYSE Arca Equities Rule 13.2 ("Rule 13.2") currently provides a mechanism for ETP Holders to receive compensation for certain types of losses. The Exchange proposes to amend Rule 13.2 in several respects.

First, the Exchange proposes to amend Rule 13.2(a) to specify that the limitation of liability set forth in that paragraph would apply to ETP Holders' successors, representatives, and customers. Pursuant to proposed Rule 13.2(a), except as otherwise expressly provided in the Exchange's rules, neither the Corporation nor its Directors, officers, committee members, employees, or agents shall be liable to ETP Holders of the Corporation, or successors, representatives, or customers thereof, or to persons associated therewith, for the specified types of losses, expenses, damages, or claims.

Second, the Exchange proposes to amend Rule 13.2(b), which describes certain prerequisites for qualifying for compensation. Specifically, Rule 13.2(b) currently requires, among other things, that "the Corporation has acknowledged receipt of" the order. As proposed, Rule 13.2(b) would require, among other things, that "the Corporation has received" the order.

Third, the Exchange proposes to amend Rule 13.2(b) to eliminate the daily liability caps. Rule 13.2(b)(1) currently provides that, as to any one or more claims made by a single ETP Holder growing out of the use or enjoyment of the facilities afforded by the Corporation on a single trading day, the Corporation will not be liable in excess of the larger of \$100,000, or the amount of any recovery obtained by the Corporation under any applicable insurance maintained by the Corporation. Rule 13.2(b)(2) currently provides that, as to the aggregate of all claims made by all ETP Holders growing out of the use or enjoyment of the facilities afforded by the Corporation on a single trading day, the Corporation will not be liable in excess of the larger of \$250,000, or the amount of the recovery obtained by the Corporation under any applicable insurance maintained by the Corporation. Rule 13.2(b)(3) currently provides that, as to the aggregate of all claims made by all ETP Holders growing out of the use or enjoyment of the facilities afforded by the Corporation during a single calendar month, the Corporation will not be liable in excess of the larger of \$500,000,

or the amount of the recovery obtained by the Corporation under any applicable insurance maintained by the Corporation.⁵ The Exchange proposes to eliminate the daily liability caps in Rules 13.2(b)(1) and (2), and retain the monthly liability cap in Rule 13.2(b)(3).⁶ The Exchange also proposes to apply the elimination of the daily liability caps retroactively to March 1, 2017, so that ETP Holders may be fully compensated for losses incurred in connection with a system issue that occurred on March 20, 2017.⁷

Fourth, the Exchange proposes to amend the time frame and clarify the manner in which ETP Holders are required to submit notice of claims for compensation. Rule 13.2(c) currently requires ETP Holders to provide written notice of claims no later than the opening of trading on the next business day following the day on which the use or enjoyment of the Corporation's facilities giving rise to the claims occurred. The Exchange proposes to require ETP Holders to submit written notice of claims for compensation pursuant to Rule 13.2(b) no later than noon Eastern Time on the next business day following the day on which the use or enjoyment of the Corporation's facilities gave rise to such claims.⁸

III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.⁹ In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,¹⁰ 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

⁵ Rule 13.2(c) currently provides that, if all of the claims arising out of the use or enjoyment of the facilities afforded by the Corporation cannot be fully satisfied because in the aggregate they exceed the applicable maximum amount of liability provided for in Rule 13.2(b), then the maximum amount shall be allocated among all such claims arising on a single trading day or during a single calendar month, as applicable, based on the proportion that each such claim bears to the sum of all such claims.

⁶ In connection with this change, the Exchange also proposes conforming changes in Rule 13.2(c) to eliminate the reference to allocation among claims arising "on a single trading day."

⁷ See Notice, *supra* note 3, at 26968.

⁸ See proposed Rule 13.2(d).

⁹ 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).

¹⁰ 15 U.S.C. 78f(b)(5).

⁴³ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 80866 (June 6, 2017), 82 FR 26967 ("Notice").

⁴ For a more detailed description of the proposed rule change, see Notice, *supra* note 3.

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.

The Commission believes that the proposal to eliminate the daily liability caps in Rules 13.2(b)(1) and (2) could result in more ETP Holders receiving fuller compensations on their claims.¹¹ The proposal could also reduce the risk that losses suffered by an ETP Holder would be treated differently depending on whether other ETP Holders suffered losses on the same day.¹² In addition, the Commission notes that, under the proposal, the maximum amount of compensation would continue to be proportionally allocated if claims arising during a single calendar month exceed the monthly liability cap.¹³

With respect to the Exchange's proposal to retroactively apply the elimination of the daily liability caps, the Commission notes that approval of the proposal would make additional funds available to compensate ETP Holders affected by the system issue on March 20, 2017. Also, as the Exchange notes, the proposal would promote equal treatment between ETP Holders who suffered a loss on March 20, 2017 and ETP Holders who suffered a loss on a different day.¹⁴ Specifically, according to the Exchange, the proposal would enable it to fully compensate ETP Holders for claims arising from the system issue on March 20, 2017.¹⁵ Moreover, according to the Exchange, prior to March 20, 2017, it has never received a claim that exceeded the liability limits, and thus it was never prevented from fully compensating an ETP Holder.¹⁶

The Commission further believes that the other proposed changes are consistent with the Act. Specifically, the Commission believes that the addition of the text "successors, representatives or customers thereof" to Rule 13.2(a) would clarify the scope of the limitation of liability in that provision.¹⁷ As the

Exchange notes, Rule 13.2 currently does not authorize the compensation of successors, representatives, or customers of ETP Holders because the rule does not currently reference them.¹⁸ The Commission also believes that the replacement of the words "acknowledged receipt of" with the word "received" in Rule 13.2(b) would provide transparency regarding the scope of the rule.¹⁹ Finally, the Commission believes that the addition of paragraph (d) to Rule 13.2 would clarify that all claims for compensation must be submitted in writing, and would provide ETP Holders additional time to evaluate losses that may have occurred on the prior trading day, particularly if an issue occurred later in the day.²⁰

Based on the foregoing, the Commission believes that the proposed rule change is consistent with the Act.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,²¹ that the proposed rule change (SR-NYSEArca-2017-46), be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²²

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017-15910 Filed 7-27-17; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-81192; File Nos. SR-DTC-2017-005; SR-FICC-2017-009; SR-NSCC-2017-006]

Self-Regulatory Organizations; The Depository Trust Company; Fixed Income Clearing Corporation; National Securities Clearing Corporation; Notice of Filing Amendment No. 1 and Order Instituting Proceedings to Determine Whether to Approve or Disapprove Proposed Rule Changes to Adopt the Clearing Agency Stress Testing Framework (Market Risk)

July 24, 2017.

I. Introduction

On April 7, 2017, The Depository Trust Company ("DTC"), Fixed Income Clearing Corporation ("FICC"), and National Securities Clearing Corporation ("NSCC," each a "Clearing Agency," and collectively, the "Clearing Agencies"), filed with the Securities and Exchange Commission ("Commission") proposed rule changes SR-DTC-2017-005, SR-FICC-2017-009, and SR-NSCC-2017-006, respectively, pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder.² The proposed rule changes were published for comment in the **Federal Register** on April 25, 2017.³ The Commission did not receive any comment letters on the proposed rule changes. On June 7, 2017, the Commission designated a longer period for Commission Action on the proposed rule changes.⁴ On July 19, 2017, the Clearing Agencies each filed Amendment No. 1 to their respective proposed rule changes (hereinafter, "Proposed Rule Change"). Amendments No. 1 would clarify how the Clearing Agencies would use scenarios to estimate the profits and losses ("P&L") of a member closeout. This order institutes proceedings under Section 19(b)(2)(B) of the Act⁵ to determine whether to approve or disapprove the Proposed Rule Changes.

II. Description of the Proposed Rule Changes

The Proposed Rule Changes would adopt the Clearing Agency Stress

¹¹ The Commission notes that the rules of certain other national securities exchanges also only include monthly liability caps, and no daily liability caps. *See, e.g.,* Nasdaq Stock Market LLC ("Nasdaq") Rule 4626.

¹² *See* Notice, *supra* note 3, at 26968.

¹³ *See* proposed changes to Rule 13.2(c). As described above, the Exchange also proposes to make conforming changes in Rule 13.2(c) to eliminate the reference to allocation among claims arising "on a single trading day." *See supra* notes 5-6.

¹⁴ *See* Notice, *supra* note 3, at 26968.

¹⁵ *See id.* at 26969.

¹⁶ *See id.*

¹⁷ The Commission notes that this change is consistent with the rules of certain other national

securities exchanges. *See, e.g.,* Bats BZX Exchange, Inc. Rule 11.16(a).

¹⁸ *See* Notice, *supra* note 3, at 26967.

¹⁹ The Commission notes that this change is consistent with the rules of certain other national securities exchanges. *See, e.g.,* New York Stock Exchange LLC Rule 18(b).

²⁰ The Commission notes that this change is consistent with the rules of certain other national securities exchanges. *See, e.g.,* Nasdaq Rule 4626(b)(6).

²¹ 15 U.S.C. 78s(b)(2).

²² 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ *See* Securities Exchange Act Release No. 80485 (April 19, 2017), 82 FR 19131 (April 25, 2017) (SR-DTC-2017-005; SR-FICC-2017-009; SR-NSCC-2017-006) ("Notice").

⁴ *See* Securities Exchange Act Release No. 80876 (June 7, 2017), 82 FR 27091 (June 13, 2017) (SR-DTC-2017-005; SR-FICC-2017-009; SR-NSCC-2017-006).

⁵ 15 U.S.C. 78s(b)(2)(B).

Testing Framework (Market Risk) (“Framework”), which would set the Clearing Agencies’ procedures for identifying, measuring, monitoring, and managing their credit exposures to members. Although the Framework would be a rule of each Clearing Agency, the Proposed Rule Changes do not require any changes to the Rules, By-Laws and Organizational Certificate of DTC (“DTC Rules”), the Rulebook of GSD (“GSD Rules”), the Clearing Rules of MBSD (“MBSD Rules”), or the Rules & Procedures of NSCC (“NSCC Rules”), as the Framework would be a standalone document.⁶

In general, the Framework would describe the stress-testing practices adopted by the Clearing Agencies. The Clearing Agencies designed their stress testing to ensure the sufficiency of each Clearing Agency’s total prefunded-financial resources.⁷ The Framework would describe (i) the sources of each Clearing Agency’s total prefunded-financial resources; (ii) the Clearing Agencies’ stress-testing methodologies; (iii) the Clearing Agencies’ stress-testing governance and execution processes; and (iv) the Clearing Agencies’ model-validation practices.⁸

A. Sources of Prefunded-Financial Resources

The Framework would outline the prefunded-financial resources and related stress-testing methodologies of the Clearing Agencies. The Framework would begin by describing the applicable regulatory requirements, with respect to credit risk management, of each Clearing Agency and how the Clearing Agencies address those requirements.⁹ The Framework would address these requirements by describing how the Clearing Agencies maintain what each deems to be sufficient prefunded-financial resources to cover fully their credit exposures to each of their respective members with a high degree of confidence.¹⁰ The

Framework would also describe how the Clearing Agencies maintain additional prefunded-financial resources that, at a minimum, would enable them to cover a wide range of foreseeable stress scenarios that include, but are not limited to, the default of the affiliated family of members (“Affiliated Family”) that would potentially cause the largest aggregate credit exposure to the Clearing Agency in extreme but plausible market conditions (“Cover One Requirement”).¹¹ Because the credit risks and prefunded-financial resources of each Clearing Agency differ, the Framework would describe the prefunded-financial resources and related stress-testing methodologies of the Clearing Agencies separately.¹²

With respect to FICC and NSCC, the Framework would describe that such prefunded-financial resources are their respective clearing funds, containing deposits from their members of both cash and eligible securities.¹³ The Framework would describe that such deposits are calculated for each individual member pursuant to the GSD Rules, MBSD Rules, or NSCC Rules, as applicable, and each member’s deposits would be referred to in the Framework as its “Required Deposit.”¹⁴

With respect to DTC, the Framework would describe that its prefunded financial resources are cash deposits to its “Participants Fund.”¹⁵ The Framework would also describe that DTC may use its risk management control, the “Collateral Monitor,” to monitor and assure that the settlement obligations of each member are fully collateralized.¹⁶

B. Stress-Testing Methodology

The Framework would describe the stress-testing methodologies that the Clearing Agencies use to test the sufficiency of their total prefunded-financial resources against Cover One Requirements. The Framework would state that the stress testing would be designed to identify potential weaknesses in the methodologies used to calculate members’ Required Deposits and to determine collateral haircuts.¹⁷

The Framework would describe in detail the three key components of the development of stress-testing methodologies:

1. *Risk Identification.* The Clearing Agencies would identify the principal credit-risk drivers that are representative and specific to each Clearing Agency’s clearing and/or collateral portfolio under stressed market conditions.¹⁸

2. *Scenario Development.* The Clearing Agencies would construct comprehensive and relevant sets of extreme but plausible historical and hypothetical stress scenarios for the identified risk drivers.¹⁹ The Framework would describe how the Clearing Agencies would develop and select both historical and hypothetical scenarios that reflect stressed market conditions.²⁰ Historical scenarios would be based on stressed market conditions that occurred on specific dates in the past.²¹ Contrastingly, hypothetical stress scenarios would be theoretical market conditions.²²

3. *Risk Measurement and Aggregation.* The Clearing Agencies would calculate the risk metrics of each Clearing Agency’s actual portfolio to estimate the P&L of a close out over a suitable stressed period of risk, deficiencies, and coverage ratios.²³ The Framework would describe how the Clearing Agencies would develop P&L estimation methodologies, and how they would calculate risk metrics that are applicable to such methodologies under the chosen stress-testing scenarios.²⁴ The Clearing Agencies could use a number of P&L methodologies for stress-testing purposes, including risk sensitivity, index mapping, and actual or approximate historical shock approaches.²⁵

The Framework would further describe the stress-testing methodology by stating that the Clearing Agencies would calculate member stress deficiencies,²⁶ Affiliated Family

⁶ Available at <http://www.dtcc.com/en/legal/rules-and-procedures>. FICC is comprised of two divisions: The Government Securities Division (“GSD”) and the Mortgage-Backed Securities Division (“MBSD”). Each division serves as a central counterparty, becoming the buyer and seller to each of their respective members’ securities transactions and guarantying settlement of those transactions, even if a member defaults. GSD provides, among other things, clearance and settlement for trades in U.S. Government debt issues. MBSD provides, among other things, clearance and settlement for trades in mortgage-backed securities. GSD and MBSD maintain separate sets of rules, margin models, and clearing funds. Notice at 19131.

⁷ Notice, 82 at 19132.

⁸ *Id.*

⁹ *Id.*

¹⁰ *Id.*

¹¹ See 17 CFR 240.17Ad–22(e)(4)(iii).

¹² Notice, 82 at 19132.

¹³ *Id.* Any eligible security is subject to a haircut. GSD Rule 4 (Clearing Fund and Loss Allocation), MBSD Rule 4 (Clearing Fund and Loss Allocation), and NSCC Rule 4 (Clearing Fund), *supra* note 4.

¹⁴ *Id.*

¹⁵ *Id.* DTC Rule 4 (Participants Fund and Participants Investment). *Supra* note 4.

¹⁶ Notice, 82 at 19132. “Collateral Monitor” is defined in DTC Rule 1, Section 1 (Definitions), and its calculation is further provided for in the DTC Settlement Service Guide of the DTC Rules. *Supra* note 4.

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *Id.*

²¹ Notice, 82 at 19133.

²² *Id.*

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.*

²⁶ The Framework would define “member stress deficiency” for each scenario as, with respect to FICC and NSCC, the stress loss exceeding the applicable member’s Required Deposits. The Framework would define “member stress deficiency” for each scenario at DTC as the shortfall of a member’s Collateral Monitor. *Id.*

deficiencies,²⁷ and Cover One Ratios daily.²⁸

The Framework would further state that FICC and NSCC would consider non-Cover-One Ratio coverages, such as comparing member stress deficiencies against such member's known financial resources (e.g., equity capital base), to keep abreast of potential financial vulnerabilities facing such member.²⁹ Additionally, the Framework would state that DTC would also test the adequacy of its collateral haircuts by measuring "Haircut Deficiency" as the amount of stress losses exceeding the haircut applied to collateral securities.³⁰

Moreover, the Framework would state that the Clearing Agencies measure both specific and generic wrong way risk for each Clearing Agency's members and Affiliated Families.³¹ To measure specific wrong way risk, for each given Member and its Affiliated Family and each given scenario, the securities issued by the Affiliated Family would be subject to shocks that reflect the default of a Member's Affiliated Family. To measure general wrong way risk, the Framework would apply historical scenarios during the 2008 financial crisis to securities issued by the Affiliated Family as well as securities issued by the non-Affiliated Family.

The Framework would also describe the reverse stress-testing analyses that are performed by FICC and NSCC on at least a semi-annual basis.³² These analyses provide FICC and NSCC, as central counterparties, another means for testing the sufficiency of the Clearing Agencies' respective prefunded financial resources.³³ In conducting reverse stress-testing, FICC and NSCC would utilize scenarios of multiple defaults, extreme market shocks, or shocks for other risk factors, which would cause those Clearing Agencies, as applicable, to exhaust all of their respective prefunded financial resources.³⁴

C. Stress-Testing Governance and Execution Process

The Framework would describe the Clearing Agencies' stress-testing governance and execution processes. Stress testing would be conducted daily for each of the Clearing Agencies, and stress-testing risk metrics also would be generated each day.³⁵ The Cover One Ratios and member stress deficiencies would be monitored against pre-established thresholds.³⁶ Breaches of these pre-established thresholds would initially be subject to more detailed studies to identify any potential impact to the applicable Clearing Agencies' Cover One Requirement.³⁷ The Framework would describe that, to the extent such studies indicate a potential impact to a Clearing Agency's Cover One Requirement, the threshold breach would be escalated internally and analyzed to determine if (i) there is a need to adjust the stress-testing methodology, or (ii) the threshold breach indicates an issue with a particular member.³⁸ Based on these analyses, the Clearing Agencies would determine the appropriate course of action.³⁹

D. Model Validation

The Framework would describe the process the Clearing Agencies would use to validate their stress-testing procedures. The Clearing Agencies would conduct comprehensive analyses of daily stress-testing results, the existing scenario sets (including any changes to such scenarios for the period since the last review), and the performance of the stress-testing methodologies along with key underlying parameters and assumptions.⁴⁰ These analyses would be performed at least monthly and would be conducted to assess whether each Clearing Agency's stress-testing components appropriately determine the sufficiency of the Clearing Agency's prefunded-financial resources.⁴¹ The Framework would state that such analyses may occur more frequently than monthly if, for example, (i) the products cleared or markets served by a Clearing Agency display high volatility or become less liquid, or (ii) the size or concentration of positions held by the

applicable Clearing Agency's members increases significantly.⁴²

The Framework would state that the results of these analyses are reviewed monthly by the DTCC Enterprise Stress Testing Council.⁴³ The Framework would also state that daily stress-testing results are summarized and reported monthly to the DTCC Risk Management Committee.⁴⁴ Finally, the Framework would state that stress-testing methodologies and related models are subject to independent model validation on at least an annual basis.⁴⁵

E. Notice of Filing of Amendment No. 1

As originally proposed, the Framework stated that it would use scenarios to measure specific and generic wrong way risk. The Clearing Agencies filed Amendment No. 1 to clarify that to capture specific wrong way risk, for each given Member and its Affiliated Family and each given scenario, the securities issued by the Affiliated Family would be subject to shocks that reflect the default of a Member's Affiliated Family. To capture general wrong way risk, the Framework would apply historical scenarios during the 2008 financial crisis to securities issued by the Affiliated Family as well as securities issued by the non-Affiliated Family.

III. Proceedings To Determine Whether To Approve or Disapprove the Proposed Rule Changes and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act⁴⁶ to determine whether the Proposed Rule Changes should be approved or disapproved. Institution of proceedings is appropriate at this time in view of the legal and policy issues raised by the Proposed Rule Changes. As noted above, institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, the Commission seeks and encourages interested persons to comment on the Proposed Rule Changes, and provide arguments to support the Commission's analysis as to whether to approve or disapprove the Proposed Rule Changes.

Pursuant to Section 19(b)(2)(B) of the Act,⁴⁷ the Commission is providing notice of the grounds for disapproval under consideration. The Commission is

²⁷ The Framework would define "Affiliated Family deficiency" as the aggregate of all member stress deficiencies within the applicable Affiliated Family. *Id.*

²⁸ The Framework would define "Cover One Ratio" as the ratio of Affiliated Family deficiency over the total value of the relevant Clearing Agency's clearing fund (or, for DTC, the Participants Fund), excluding the value of the applicable Affiliated Family's Required Deposits. *Id.*

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.*

³² *Id.*

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.*

³⁶ According to the Clearing Agencies, risk-threshold levels are chosen to assist each Clearing Agency in achieving a high degree of confidence that its Cover One Requirement is met daily. *Id.*

³⁷ *Id.*

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Id.*

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ 15 U.S.C. 78s(b)(2)(B).

⁴⁷ *Id.*

instituting proceedings to allow for additional analysis of the Proposed Rule Changes' consistency with the Act and the rules thereunder. Specifically, the Commission believes that the Proposed Rule Changes raise questions as to whether they are consistent with (i) Section 17A(b)(3)(F) of the Act,⁴⁸ which requires, in part, that clearing agency rules be designed to assure the safeguarding of securities in the custody or control of the clearing agency and, in general, protect investors and the public interest, and (ii) Rule 17Ad-22(e)(4) under the Act, which requires, in general, that each covered clearing agency establish, implement, maintain and enforce written policies and procedures reasonably designed to, among other things, effectively identify, measure, monitor, and manage their credit exposures to participants and those arising from its payment, clearing, and settlement processes.⁴⁹

As discussed above, pursuant to the Proposed Rule Changes, Clearing Agencies would adopt the Framework, which would procedures for identifying, measuring, monitoring, and managing their credit exposures to members. The Commission solicits comment on whether the Proposed Rule Changes are consistent with Section 17A(b)(3)(F) of the Act⁵⁰ and Rule 17Ad-22(e)(4) under the Act.⁵¹

IV. Request for Written Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to issues raised by the Proposed Rule Changes. In particular, the Commission invites the written views of interested persons concerning whether the Proposed Rule Changes are consistent with Sections 17A(b)(3)(F) of the Act and Rules 17Ad-22(e)(4) under the Act, cited above, or any other provision of the Act, or the rules and regulations thereunder. Interested persons are invited to submit written data, views, and arguments on or before August 14, 2017. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal on or before August 18, 2017. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or

- Send an email to rule-comments@sec.gov. Please include File Number SR-FICC-2017-002 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 Numbers SR-DTC-2017-005, SR-FICC-2017-009, or SR-NSCC-2017-006. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the Proposed Rule Changes that are filed with the Commission, and all written communications relating to the Proposed Rule Change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings also will be available for inspection and copying at the principal office of the Clearing Agencies and on DTCC's Web site (<http://dtcc.com/legal/sec-rule-filings.aspx>). All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Numbers SR-DTC-2017-005, SR-FICC-2017-009, or SR-NSCC-2017-006 and should be submitted on or before August 14, 2017. If comments are received, any rebuttal comments should be submitted on or before August 18, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁵²

Eduardo A. Aleman,
Assistant Secretary.

[FR Doc. 2017-15905 Filed 7-27-17; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-81196; File No. SR-FINRA-2017-025]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing of a Proposed Rule Change Relating to the Definition of Non-Public Arbitrator

July 24, 2017.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² notice is hereby given that on July 10, 2017, Financial Industry Regulatory Authority, Inc. ("FINRA") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by FINRA. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to amend FINRA Rule 12100 of the Code of Arbitration Procedure for Customer Disputes ("Customer Code") and FINRA Rule 13100 of the Code of Arbitration Procedure for Industry Disputes ("Industry Code" and together, "Codes"), to define a non-public arbitrator to mean a person who is otherwise qualified to serve as an arbitrator, and is disqualified from service as a public arbitrator under the Codes.

The text of the proposed rule change is available on FINRA's Web site at <http://www.finra.org>, at the principal office of FINRA and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

⁴⁸ 15 U.S.C. 78q-1(b)(3)(F).

⁴⁹ 17 CFR 240.17Ad-22(e)(4).

⁵⁰ 15 U.S.C. 78q-1(b)(3)(F).

⁵¹ 17 CFR 240.17Ad-22(e)(4).

⁵² 17 CFR 200.30-3(a)(57).

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

FINRA classifies arbitrators under the Codes as either “non-public” or “public.” The Codes define these terms.³ The non-public arbitrator definition lists affiliations that might *qualify* a person to serve as a non-public arbitrator at the forum. Conversely, the public arbitrator definition enumerates criteria that *disqualify* an applicant from inclusion on the public arbitrator roster.

In 2015, the SEC approved amendments to the definitions of non-public arbitrator and public arbitrator in the Codes.⁴ Among other things, the amendments provided that persons who worked in the financial industry for any duration during their careers would always be classified as non-public arbitrators and the amendments added new disqualifications to the public arbitrator definition relating to an arbitrator's provision of services to parties in securities arbitration and litigation and to revenues earned from the financial industry by an arbitrator's co-workers. The amendments also broadened the disqualifications based on the activities or affiliations of an arbitrator's family members. The intent of the proposed rule change was to address concerns about arbitrator neutrality raised by forum users.⁵ For example, prior to the 2015 amendments, the Codes, with specified exceptions, permitted former financial industry employees who ended their industry affiliations to qualify as public arbitrators five years after leaving the financial industry. Forum users raised concerns about the neutrality of these individuals, and indicated that they did not believe former industry employees should ever serve as public arbitrators. In response to these concerns, the 2015 amendments eliminated the five-year cooling-off period, thereby classifying all former financial industry employees as non-public arbitrators.

Under the definitions as revised in 2015, the non-public arbitrator roster is composed of individuals who work, or worked, in the financial industry, or provide services to the financial industry or to parties engaged in

securities arbitration and litigation. The public arbitrator roster is composed of individuals who do not have any significant affiliation with the financial industry. These arbitrators have never been employed by the industry, do not provide services to the industry or to parties engaged in securities arbitration and litigation, and do not have immediate family members or co-workers who do so.

Eligibility Gap

The 2015 amendments to the arbitrator definitions created an eligibility gap whereby certain otherwise qualified arbitrators⁶ could not serve in any capacity. The eligibility gap was created when FINRA narrowed the public arbitrator definition as described above. Over 800 public arbitrators were disqualified from the public arbitrator roster under the revised public arbitrator definition. In addition, more than 100 of these disqualified arbitrators did not meet any of the criteria outlined in the non-public arbitrator definition for service on the non-public arbitrator roster. As a result of this eligibility gap, FINRA removed them from service at the forum.

In most instances, the basis for removal from the roster was an affiliation relating to an arbitrator's family members or co-workers. For example, a real estate attorney in a large law firm that has a securities practice would be disqualified from service as a public arbitrator if the firm derived \$50,000 or more in a calendar year from providing services to securities entities. In addition, employment as a real estate attorney would not qualify the arbitrator to serve as a non-public arbitrator under the current definition. Therefore, the arbitrator falls into the eligibility gap. In addition to losing over 100 public arbitrators, the eligibility gap required FINRA to reject over 140 arbitrator applicants in 2016 who met FINRA's minimum arbitrator qualifications.

Proposed Rule Change

FINRA is proposing to amend the Codes to allow FINRA to appoint individuals to the non-public arbitrator roster if they meet FINRA's general arbitrator qualification criteria,⁷ but cannot be classified as public arbitrators. FINRA would amend the non-public arbitrator definition to delete

the specific criteria for inclusion on the non-public arbitrator roster. Instead, Rules 12100(r) and 13100(r) would provide that the term “non-public arbitrator” means a person who is otherwise qualified to serve as an arbitrator, and is disqualified from service as a public arbitrator.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,⁸ which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. Specifically, the proposed rule change would close the eligibility gap, simplify the non-public arbitrator definition, and provide greater choice for parties during the panel selection process.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. A key focus of the 2015 amendments was the elimination of certain individuals from the public arbitrator roster. FINRA's intent was not to prevent these individuals from serving in any capacity. Hundreds of arbitrators or arbitrator applicants who formerly qualified to serve as public arbitrators are now unable to serve as arbitrators in the forum. As a result, the pool of eligible arbitrators has decreased, and FINRA is forced to turn away new candidates who would have been eligible to serve but for the recent amendments.

The proposed rule change would permit these previously eligible persons to serve as non-public arbitrators. While not changing the public arbitrator definition as approved by the SEC in 2015, the proposed rule change would expand the pool of candidates eligible to serve as non-public arbitrators. FINRA considered revising the public arbitrator definition to close the eligibility gap, but chose to maintain the recently approved criteria that exclude individuals who have any significant affiliation with the financial industry. Increasing the number of qualified arbitrators benefits all parties who come before the forum because it permits parties to consider additional arbitrators during panel selection and may reduce

³ See FINRA Rules 12100(r) and 13100(r) for the definition of non-public arbitrator and Rules 12100(y) and 13100(x) for the definition of public arbitrator.

⁴ See Securities Exchange Act Rel. No. 74383 (February 26, 2015), 80 FR 11695 (March 4, 2015).

⁵ *Regulatory Notice 15-18* (Definitions of Non-Public and Public Arbitrator) describes the changes made to the arbitrator definitions.

⁶ Unless waived by FINRA at its discretion, arbitrator applicants must have a minimum of five years of paid business and/or professional experience and at least two years of college-level credits. Qualification criteria can be found at <http://www.finra.org/arbitration-and-mediation/finra-arbitrators>.

⁷ See *id.*

⁸ 15 U.S.C. 78o-3(b)(6).

costs that arise due to an insufficient pool of qualified arbitrators such as the costs associated with arbitrators traveling from other hearing locations. Further, readmitting previously qualified persons increases the pool of experienced arbitrators, which strengthens the forum.

The proposal would impose no direct or indirect costs on persons previously eliminated from acting as arbitrators, new candidates for arbitrator, or parties accessing the forum.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

- (A) By order approve or disapprove such proposed rule change, or
- (B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-FINRA-2017-025 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090. All submissions should refer to File Number SR-FINRA-2017-025. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will

post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of FINRA. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR-FINRA-2017-025 and should be submitted on or before August 18, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁹

Eduardo A. Aleman,
Assistant Secretary.

[FR Doc. 2017-15909 Filed 7-27-17; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-81195; File No. SR-IEX-2017-11]

Self-Regulatory Organizations; Investors Exchange LLC; Notice of Filing of Amendment No. 3 and Order Granting Accelerated Approval of Proposed Rule Change, as Modified by Amendment No. 3, To Modify the Manner in Which the Exchange Opens Trading for Non-IEX-Listed Securities

July 24, 2017.

I. Introduction

On April 13, 2017, Investors Exchange LLC ("IEX" or the "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: (i) Amend IEX Rule 11.231 to modify the manner in which the Exchange opens trading for non-IEX-listed securities beginning at the start of Regular Market Hours; and (ii) amend IEX Rules 11.190 and 11.220 to specify the order types eligible to participate in the proposed opening process for non-IEX listed securities and priority of such orders. The proposed rule change was published for comment in the **Federal Register** on April 28, 2017.³ On May 19, 2017, IEX filed Amendment No. 1 to the proposal. On June 9, 2017, IEX consented to an extension of time for the Commission to act on the proposal until July 5, 2017.⁴ On June 22, 2017, IEX filed Amendment No. 2 to the proposal, which superseded and replaced Amendment No. 1 in its entirety. On June 29, 2017, IEX filed Amendment No. 3 to the proposal, which superseded and replaced Amendment No. 2 in its entirety.⁵ Also on June 29, 2017, pursuant to Section 19(b)(2) of the Act,⁶ 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 approve or disapprove the proposed rule change.⁷ The Commission received no comments on the proposed rule change. The Commission is publishing this notice to solicit comment on Amendment No. 3 to the proposed rule change from interested persons, and is approving the proposed rule change, as modified by Amendment No. 3, on an accelerated basis.

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 80514 (April 24, 2017), 82 FR 19763 ("Notice").

⁴ See letter from Claudia Crowley, Chief Regulatory Officer, IEX, to Richard Holley, Assistant Director, Division of Trading and Markets, Commission, dated June 9, 2017.

⁵ Amendment No. 3 revised the proposal to: (i) Provide additional clarity regarding the process for determining the opening match price; (ii) modify the definition of "Cross Tie Breaker" to account for the requirement under the National Market System Plan to Implement a Tick Size Pilot Program ("Tick Size Pilot") that certain securities be traded in nickel increments; and (iii) correct certain typographical errors. Amendment No. 3 also revised the proposal to fix an error in the proposed rule text in Amendment No. 2 and correct additional typographical errors. Amendment No. 3 is available at: <https://www.sec.gov/comments/sr-idx-2017-11/idx201711-1831518-154558.pdf>.

⁶ 15 U.S.C. 78s(b)(2).

⁷ See Securities Exchange Act Release No. 81052 (June 29, 2017), 82 FR 31377 (July 6, 2017). The Commission designated July 27, 2017 as the date by which the Commission shall approve or disapprove, or institute proceedings to determine whether to approve or disapprove, the proposed rule change.

⁹ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

II. Description of the Proposed Rule Change, as Modified by Amendment No. 3

IEX has proposed to amend IEX Rule ("Rule") 11.231 to modify the manner in which the Exchange opens trading for non-IEX-listed securities beginning at the start of Regular Market Hours (the "Opening Process").⁸ According to the Exchange, it will attempt to perform the Opening Process in each non-IEX-listed security pursuant to which eligible interest resting on the Exchange's Continuous Book in the Pre-Market Session or queued for the Regular Market Session will be matched, to the greatest extent possible, at a single price at the start of the Regular Market Session.⁹ The Exchange explained that the proposed Opening Process is designed to efficiently maximize the number of shares executed at a single price that is reflective of the broader market for the security.¹⁰

Currently, at the beginning of the Pre-Market Session, the Exchange begins accepting limit orders with certain time-in-force indicators that are immediately eligible for execution.¹¹ Separately, the Exchange accepts during the Pre-Market Session limit orders that are only eligible for execution starting with the Regular Market Session, including orders with a time-in-force of DAY or Good 'til Extended Day ("GTX") and pegged orders with a time-in-force of DAY. The Exchange queues these orders in sequence until the start of the Regular Market Session.¹² Currently, at the start of Regular Market Hours, the Exchange releases these queued orders in relative time priority, after which they are eligible for trading in the Regular Market Session, subject to User instructions and market conditions.¹³

Under proposed Rule 11.231(a), IEX would maintain a separate "Cross Book" on which certain types of orders would

queue prior to Regular Market Hours.¹⁴ Orders on the new Cross Book, together with orders resting on the Order Book during the Pre-Market Session (*i.e.*, orders on the Continuous Book), would be eligible for execution in the new Opening Process.¹⁵ Collectively, the orders eligible for execution in the Opening Process would be "Cross Eligible Orders."¹⁶ Orders on the Continuous Book and on the Cross Book would be ranked and maintained for the Opening Process pursuant to Rule 11.220(a)(2), as described below.¹⁷

Currently, Users may only submit market orders during the Regular Market Session and the System rejects market orders submitted during the Pre-Market or Post-Market Sessions.¹⁸ By default, the System currently rejects market orders with a time-in-force of DAY.¹⁹ Under proposed Rule 11.190(a)(2)(E), the Exchange will allow non-routable DAY market orders submitted in the Pre-Market Session to queue for the Opening Process.²⁰

Orders resting on the Order Book will be ranked and maintained for the Opening Process based on price-display-time priority.²¹ Once booked, a Cross

Eligible Order would maintain its time priority until one of the following occur, at which time the order would receive a new timestamp: (i) It is incremented or re-priced, in the case of an order on the Cross Book; (ii) it is re-priced by the System in response to changes in the NBBO, in the case of a pegged order on the Cross Book; or (iii) it experiences an event specified in Rule 11.220(a)(1)(C), in the case of an order on the Continuous Book.²²

Under proposed Rule 11.231(b), at the start of Regular Market Hours, the Exchange will perform the Opening Process in which it matches buy and sell Cross Eligible Orders that are executable at the single price determined by IEX (the "Opening Match Price"), as described further below.²³ First, market orders would execute at the Opening Match Price in time priority. Second, remaining Cross Eligible Orders priced *more aggressively* than the Opening Match Price would execute in price-display-time priority at the Opening Match Price. Finally, remaining Cross Eligible Orders priced *equal* to the Opening Match Price would execute in display-time priority at the Opening Match Price. This process, called the "Opening Match," would continue until either there is no remaining volume or there is an imbalance of Cross Eligible Orders.²⁴

Proposed Rule 11.231(c) details the Exchange's process for determining the Opening Match Price, and will take into consideration the current pricing at away markets.²⁵ The Opening Match

which would be ranked by their current booked price. *See* proposed Rule 11.220(a)(2)(A). Displayed orders and displayed portions of Cross Eligible Orders would have precedence over non-displayed orders and non-displayed portions of Cross Eligible Orders at a given price. *See* proposed Rule 11.220(a)(2)(B).

²² *See* proposed Rule 11.220(a)(2)(C). Pursuant to proposed Rule 11.231(a)(1)(ii) and (iii), respectively, when exercising price discretion, primary peg and discretionary peg orders would maintain time priority at their resting price, but would be prioritized behind any non-displayed interest at the Opening Match Price for the duration of the Opening Process. *See* proposed Rule 11.220(a)(2)(C)(v). In addition, an order from which a Minimum Quantity instruction is removed, therefore causing the order to become a Cross Eligible Order, would also receive a new timestamp. *See* proposed Rule 11.220(a)(2)(C)(iii).

²³ *See* proposed Rule 11.231(b).

²⁴ *See* proposed Rule 11.231(b)(1). AGID modifiers, as defined in Rule 11.190(e), would not be supported for executions in the Opening Match, but would be enforced on all unexecuted shares released to the Order Book following the Opening Match. *See id.*

²⁵ "Away Protected NBB" and "Away Protected NBO" would be defined as the national best bid or offer, respectively, that is a Protected Quotation and not a quotation of the Exchange. *See* proposed Rule 11.231(c)(1)(i). "Away Protected Bid" and "Away Protected Offer" would be defined as a Protected

Continued

⁸ The Exchange also would retitle this rule as "Regular Market Session Opening Process for Non-IEX-Listed Securities." The terms "Regular Market Hours" or "Regular Market Session" mean the time between 9:30 a.m. and 4:00 p.m. Eastern Time. *See* Rule 1.160(gg). The terms "Pre-Market Hours" or "Pre-Market Session" mean the time between 8:00 a.m. and 9:30 a.m. Eastern Time. *See* Rule 1.160(z). The terms "Post-Market Hours" or "Post-Market Session" mean the time between 4:00 p.m. and 5:00 p.m. Eastern Time. *See* Rule 1.160(aa).

⁹ *See* Notice, *supra* note 3, at 19764.

¹⁰ *See id.*

¹¹ *See* Rules 11.190(c)(1) (Immediate-or-Cancel), 11.190(c)(2) (Fill or Kill), 11.190(c)(5) (System Session), and 11.190(c)(6) (Good 'til Time); *see also* Notice, *supra* note 3, at 19763.

¹² *See* Rules 11.190(c)(3) and (4) and 11.231(a); *see also* Notice, *supra* note 3, at 19763.

¹³ *See* Rule 11.231(c); *see also* Notice, *supra* note 3, at 19763. The term "User" has the meaning set forth in Rule 1.160(qq).

¹⁴ *See* proposed Rule 11.231(a). Specifically, orders with a time-in-force of DAY and limit orders with a time-in-force of GTX would queue on the Cross Book and be eligible for execution in the proposed new Opening Process. *See id.*

¹⁵ *See id.* The term "Order Book" has the meaning set forth in Rule 1.160(p).

¹⁶ *See id.* Orders with a Minimum Quantity as defined in Rule 11.190(b)(11) would not be eligible for execution in the Opening Process and therefore would not be Cross Eligible Orders. *See id.* The Exchange has proposed to amend Rule 11.190(b)(11)(F) to specify that Minimum Quantity orders are not eligible to participate in the Opening Process. *See* proposed Rule 11.190(b)(11)(F).

¹⁷ *See* proposed Rule 11.231(a)(1). For additional detail concerning the price at which pegged orders and limit orders would be ranked and eligible for execution, *see* Notice, *supra* note 3, at 19764.

¹⁸ *See* Rule 11.190(a)(2)(E). The term "System" has the meaning set forth in Rule 1.160(nn).

¹⁹ *See* Rule 11.190(a)(2)(E)(iii). The Exchange permits a User to elect for its market orders with a time-in-force of DAY to be accepted and eligible to trade or route during the Regular Market Session. Pursuant to this election, the System treats market orders marked DAY as having a time-in-force of IOC. *See id.*

²⁰ *See* proposed Rule 11.190(a)(2)(E). The Exchange explained that market orders with a time-in-force of DAY that are entered during the Pre-Market Session and are designated to route pursuant to Rule 11.230(c) would be rejected upon entry. *See* Notice, *supra* note 3, at 19764 n. 6. Additionally, the Exchange noted that orders with a time-in-force of IOC or FOK do not rest on the Order Book and therefore would be ineligible to participate in the Opening Process. *See* Notice, *supra* note 3, at 19764.

²¹ *See* proposed Rule 11.220(a)(2). Market orders would have precedence over limit orders. Cross Eligible Orders resting on the Continuous Book would be ranked by the price at which they are resting on the Continuous Book. Cross Eligible Orders resting on the Cross Book would be ranked by their limit price, if any, except for pegged orders,

would be “collared” in that it generally will have to occur within specified upper and lower threshold prices, known as the “Cross Price Constraint,” which will generally be set at the Away Protected NBB and Away Protected NBO.²⁶ If, at the time of the Opening Process, there is a crossed market in a particular security and the upper threshold price of the Cross Price Constraint is below the lower threshold price, no Opening Match would occur for that security, orders eligible to post on the Order Book would price slide in accordance with the price sliding process in IEX Rule 11.190(h), and the security would open for trading on the Exchange in accordance with prevailing market session rules.²⁷

As described further below, in certain circumstances when needed to help determine the Opening Match Price, the Exchange will consider the price of the most current Order Collar Reference Price pursuant to Rule 11.190(f),²⁸ rounded to the nearest minimum price variant (“MPV”) or Midpoint Price²⁹ at the start of the Opening Process, whichever is closer (the “Cross Tie Breaker”).³⁰ The Exchange explained

Bid or Protected Offer, respectively, that is not a quotation of the Exchange. *See* proposed Rule 11.231(c)(1)(ii). “Protected Bid,” “Protected Offer,” and “Protected Quotation” have the meaning set forth in Rule 1.160(bb).

²⁶ Specifically, the upper threshold price of the Cross Price Constraint would be equal to the Away Protected NBO, except that if an Away Protected Bid is crossing an Away Protected Offer, the upper threshold price would be equal to the greater of five cents (\$0.05) or one half of a percent (0.5%) higher than the lowest Away Protected Offer. Similarly, the lower threshold price of the Cross Price Constraint would be equal to the Away Protected NBB, except if an Away Protected Bid is crossing an Away Protected Offer, the lower threshold price would be equal to the greater of five cents (\$0.05) or one half of a percent (0.5%) lower than the highest Away Protected Bid. *See* proposed Rule 11.231(c)(1)(iii)(A) and (B).

²⁷ *See* proposed Rule 11.231(c)(1)(iii).

²⁸ The “Order Collar Reference Price” is equal to the most current of: (i) The consolidated last sale price disseminated during the Regular Market Session on the trade date; (ii) the last trade price disseminated outside of the Regular Market Session (Form T) by the SIP, which other than for the Form T designation would have been considered a valid last sale price; or (iii) if no such price exists, the prior day’s official closing price from the listing exchange. *See* Rule 11.190(f)(1)(A).

²⁹ “Midpoint Price” is defined as the midpoint of the NBBO. *See* Rule 1.160(t).

³⁰ *See* proposed Rule 11.231(c)(1)(iv); *see also* Amendment No. 3, *supra* note 5, at 27. In its proposal, the Exchange explained that if there have been no Pre-Market Session trades that qualify to update the Order Collar Reference Price and no previous official closing price is available for the security, in the interest of maintaining a fair and orderly market, the Exchange will prevent trading in the security, pursuant to Rule 11.190(f)(1)(B), by rejecting orders beginning at the start of the Pre-Market Session and will not conduct an Opening Match. *See* Notice, *supra* note 3, at 19765 n. 7. The Exchange further explained that trading would

that it included the rounding approach for the Cross Tie Breaker to avoid a potential inconsistency with the Tick Size Pilot if a Cross Tie Breaker in a non-nickel increment were to set the Opening Match Price for a pilot security required to be traded in nickel increments.³¹

Proposed Rule 11.231(c)(2) provides the Exchange’s process for determining the Opening Match Price when both an Away Protected Bid and Away Protected Offer exist for the subject security (*i.e.*, a two-sided market).³² In general, the Opening Match will occur at the price that maximizes the number of shares of Cross Eligible Orders to be executed.³³ If multiple prices are possible, resulting in a cross price range, IEX’s rule provides a series of steps it would follow to determine the Opening Match Price.³⁴

Alternatively, proposed Rule 11.231(c)(3) provides the Exchange’s process for determining the Opening Match Price if there is a lack of an Away Protected Bid, Away Protected Offer, or both, for the subject security at the time of the Opening Process (*i.e.*, a one-sided or zero-sided market).³⁵ In such cases, the Opening Match generally will occur at the price of the Cross Tie Breaker, subject to the Cross Price Constraint.³⁶

begin upon receipt of the first Order Collar Reference Price for the security. *See id.*

³¹ *See* Amendment No. 3, *supra* note 5, at 9–11. According to the Exchange, it proposed to apply this rounding logic to all non-IEX-listed securities, and not solely to the Tick Size Pilot securities required to trade in nickel increments, to maintain continuity in how the Exchange handles securities during the Opening Process and avoid introducing technical complexities into the System. *See* Amendment No. 3, *supra* note 5, at 11. The Exchange explained that non-pilot securities priced above \$1.00 would be rounded to the nearest Midpoint Price or one-penny MPV, whichever is closer. *See id.*

³² *See* proposed Rule 11.231(c)(2).

³³ *See* proposed Rule 11.231(c)(2)(i).

³⁴ *See* proposed Rule 11.231(c)(2)(ii)–(iv); *see also* Amendment No. 3, *supra* note 5, at 27. For examples of the process for determining the Opening Match Price in a two-sided market, *see* Examples 1 through 4 on pages 15 to 17 of Amendment No. 3, *supra* note 5. For additional examples of the process for determining the Opening Match Price in a two-sided market when there are non-displayed orders on the Cross Book, *see* Example 1 on pages 17–18 of Amendment No. 3, *supra* note 5, and Examples 2 through 4 in the Notice, *supra* note 3, at 19766–67. For examples of how the Exchange would round the Cross Tie Breaker in a two-sided market, *see* Examples 3 and 6 on pages 13 and 14, respectively, of Amendment No. 3, *supra* note 5.

³⁵ *See* proposed Rule 11.231(c)(3).

³⁶ *See* proposed Rule 11.231(c)(3)(i)–(ii). In its proposal, the Exchange noted that in a one-sided market where there is no Away Protected NBB or no Away Protected NBO, the Cross Tie Breaker would be compared to the available threshold price of the Cross Price Constraint (*i.e.*, the Opening Match Price would be at or above the lower threshold price, or at or below the upper threshold

After the Opening Process, all remaining unexecuted interest would be released to the Order Book for continuous trading or cancelled in accordance with the terms of the order.³⁷ Routable orders that are released to the Order Book would be routed in accordance with IEX Rule 11.230(c)(3), subject to the orders’ instructions.³⁸

If a disruption occurs that prevents the execution of the Opening Process described above, IEX will apply the contingency procedures established in proposed Rule 11.231(d). Specifically, IEX would publicly announce that no Opening Process will occur, all orders on the Order Book would be cancelled, and IEX would open the security for trading without an Opening Match.³⁹

If a security is subject to a halt, suspension, or pause in trading during the Pre-Market Session, the Exchange would not accept orders in the security, including for queuing in the Cross Book and participation in the Opening Process.⁴⁰ Orders submitted during the halt would be rejected, while orders resting on the Order Book would remain unless cancelled by the User, but would be unavailable for trading during the halt.⁴¹ If the halt, suspension, or pause remained in effect at the start of Regular Market Hours, the Opening Process would not start at the normally scheduled time, but would be conducted once the security resumes trading.⁴²

Under proposed Rule 11.231(f), pursuant to Rule 611(b)(3) of Regulation NMS and section VI(D)(6) of the Tick

price of the Cross Price Constraint, as applicable). However, in a zero-sided market, the Opening Match Price would be the Cross Tie Breaker. *See* Notice, *supra* note 3, at 19767 n. 9. For examples of the process for determining the Opening Match Price in a one-sided or zero-sided market, *see* Examples 1 through 3 on pages 18 to 19 of Amendment No. 3, *supra* note 5. For examples of how the Exchange would round the Cross Tie Breaker in a one-sided or zero-sided market, *see* Examples 1, 2, 4, and 5 on pages 12 to 14 of Amendment No. 3, *supra* note 5.

³⁷ *See* proposed Rule 11.231(b)(2). Cross Eligible Orders may remain unexecuted, in whole or in part, due to an imbalance of Cross Eligible Orders during the Opening Process. *See id.* Unexecuted Cross Eligible Orders that are priced at or outside of the Cross Price Constraint (*i.e.*, buy orders at or above the Cross Price Constraint or sell orders at or below the Cross Price Constraint) would price slide pursuant to IEX Rule 11.190(h). *See id.*

³⁸ *See id.*

³⁹ *See* proposed Rule 11.231(d). In its proposal, the Exchange noted that it would disseminate a System Status Alert, which would automatically send an email alert, twitter update, and text message to announce that no Opening Process would occur and publish such information on IEX’s Web site. *See* Notice, *supra* note 3, at 19767 n. 12.

⁴⁰ *See* proposed Rule 11.231(e).

⁴¹ *See id.*

⁴² *See id.*

Size Pilot, orders executed in the Opening Process would constitute a single-priced opening transaction by the Exchange and would be allowed to trade-through or trade-at the price of any other Trading Center's Manual or Protected Quotations.⁴³

Finally, the Exchange has proposed to make a minor conforming change to the language used to reference LULD Price Bands in Rule 11.190(a)(2).⁴⁴

III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change, as modified by Amendment No. 3, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.⁴⁵ In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,⁴⁶ which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in 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 has stated that its proposed Opening Process for non-IEX-listed securities is designed to match at a single price all eligible buy and sell orders that are resting on the Exchange's order book and available for continuous trading during the Pre-Market Session, as well as orders that have been queued until Regular Market Hours.⁴⁷ According to the Exchange, the proposed Opening Process will provide for orderly and timely openings.⁴⁸

The Commission believes that the proposed Opening Process is designed to open Regular Market Hours trading on the Exchange in non-IEX-listed securities in a fair and orderly manner, which is consistent with the protection of investors and the public interest. Currently, the Exchange does not conduct an opening process for non-listed-IEX securities that is designed to match marketable buy and sell interest

at a single price; rather, at the beginning of Regular Market Hours, the Exchange handles orders that have been queued during the Pre-Market Session by releasing them, according to their relative time priority, into continuous trading as incoming orders.⁴⁹ To the extent the Exchange's proposal helps facilitate an orderly transition to regular trading in a fair and transparent manner, the Commission believes that it is consistent with the Act.

The Commission also believes that the proposed rule change is consistent with the Act because it is designed to open Regular Market Hours trading in each non-IEX-listed security by matching as much interest as it can at a price determined through an objective process set forth in its proposed rule. The Commission notes that, under proposed Rule 11.231(c)(2), the Exchange would attempt to set the Opening Match Price in a two-sided market at the price where the maximum number of shares of Cross Eligible Orders would be executed, taking into account the prices and relative volume balance of eligible buy and sell orders resting on the Exchange in the particular security.⁵⁰ In the event that a single Opening Match Price cannot be established in a two-sided market based on the eligible interest resting on the Exchange, or in the event that there is a one-sided or zero-sided market, the Exchange would rely on the Cross Tie Breaker price to determine the Opening Match Price.⁵¹ The Commission believes that these aspects of the proposed Opening Process are consistent with Section 6(b)(5) of the Act in that they are designed to promote just and equitable principles of trade and protect investors.

Further, the Commission notes that, based on the Exchange's proposed definition of Cross Tie Breaker,⁵² which incorporates the Exchange's current definition of Order Collar Reference Price,⁵³ the Exchange effectively would rely on the most recent last sale price to determine the Opening Match Price when a single Opening Match Price cannot be determined based on the Cross Eligible Orders resting on the Exchange in a two-sided market, or when there is a one-sided or zero-sided market. The Commission also notes that the Cross Tie Breaker price (*i.e.*, the most recent last sale price) would be rounded as proposed for certain non-

IEX listed securities subject to the Tick Size Pilot in order to ensure that the Opening Match occurs at a price that is permissible under the pilot, as well as for other non-pilot non-IEX-listed securities in order to maintain continuity and reduce complexity in the Exchange's handling of securities during the Opening Process.⁵⁴ The Commission believes that relying on the most recent last sale price in these circumstances, and rounding that price as necessary, is consistent with the Act, including Section 6(b)(5) of the Act.

The Commission also notes that the Exchange has proposed to apply a Cross Price Constraint to prevent the Opening Match from occurring at a price that would be outside the Away Protected NBB and/or NBO, as applicable. The Commission believes that this collar feature of the proposed Opening Process is reasonably designed to ensure that the Opening Match occurs at a price that is within the broad market price for the security, and therefore should help to protect investors and remove impediments to and perfect the mechanism of a national market system, consistent with Section 6(b)(5) of the Act.

In addition, the Commission believes that the Exchange's proposed order handling during the Opening Process is consistent with the Act. The Commission notes that the Exchange's proposed priority hierarchy for the ranking and execution of opening-cross-eligible orders is consistent with the Exchange's order execution priority hierarchy during continuous trading.⁵⁵ Further, the Exchange has proposed to handle unexecuted opening-cross-eligible orders consistent with their terms, subject to the price sliding provisions of Rule 11.190(h) as appropriate.⁵⁶ The Commission believes that these aspects of the proposal provide continuity with the Exchange's order handling practices and should reduce the potential for investor confusion when the Exchange transitions to continuous trading.

The Commission also notes that the Exchange believes that allowing non-routable DAY market orders to be submitted and queue for the Opening Process will provide members with greater flexibility.⁵⁷ The Commission

⁴³ See proposed Rule 11.231(f).

⁴⁴ See proposed Rule 11.190(a)(2).

⁴⁵ 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).

⁴⁶ 15 U.S.C. 78f(b)(5).

⁴⁷ See Notice, *supra* note 3, at 19764.

⁴⁸ See Notice, *supra* note 3, at 19767.

⁴⁹ See Notice, *supra* note 3, at 19763.

⁵⁰ See proposed Rule 11.231(c)(2)(i) and (ii); see also Amendment No. 3.

⁵¹ See proposed Rules 11.231(c)(2)(iii) and 11.231(c)(3); see also Amendment No. 3.

⁵² See proposed Rule 11.231(c)(1)(iv); see also Amendment No. 3.

⁵³ See Rule 11.190(f).

⁵⁴ See Amendment No. 3.

⁵⁵ See proposed Rules 11.220(a)(2), 11.231(a)(1), and 11.231(b)(1); see also Notice, *supra* note 3, at 19768.

⁵⁶ See proposed Rule 11.231(b)(2).

⁵⁷ See proposed Rules 11.190(a)(2)(E) and 11.231(a); see also Notice, *supra* note 3, at 19769. The Commission notes that market orders currently may only be submitted to the Exchange in the

believes that allowing non-routable DAY market orders to queue for the Opening Process may accommodate market participants that use DAY market orders on other exchanges and therein may help promote the orderly submission of those orders to the Exchange in advance of the Regular Market Session.

Further, the Commission believes that the components of the proposal that are designed to address what would occur if a disruption prevents the execution of the opening process,⁵⁸ and what would occur if a security is subject to a halt, suspension, or pause in trading during the Pre-Market Session,⁵⁹ set forth procedures that are reasonably designed to protect investors and the public interest, and remove impediments to and perfect the mechanism of a national market system, consistent with Section 6(b)(5) of the Act.⁶⁰

Finally, the Commission notes that another national securities exchange conducts an opening process for non-listed securities,⁶¹ and the Commission received no comments on the Exchange's proposed rule change.

IV. Solicitation of Comments on Amendment No. 3

Interested persons are invited to submit written data, views, and arguments concerning whether Amendment No. 3 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-IEX-2017-11 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.

Regular Market Session, and are rejected if submitted during the Pre-Market (or Post-Market) Session. See Notice, *supra* note 3, at 19763.

⁵⁸ See proposed Rule 11.231(d).

⁵⁹ See proposed Rule 11.231(e).

⁶⁰ The Commission believes that the other components of the proposal, including proposed Rule 11.231(f) and the minor conforming change to the language used to reference LULD Price Bands in Rule 11.190(a)(2), are consistent with the Act.

⁶¹ See, e.g., BZX Rule 11.24. The Commission notes that the BZX opening process for non-listed securities is largely similar to what the Exchange has proposed, but differs in that it is designed to match eligible orders at the midpoint of the NBBO whereas the Exchange's proposed Opening Match, while bound by the Away Protected NBBO, could occur at a price other than the midpoint of the Away Protected NBBO.

All submissions should refer to File Number SR-IEX-2017-11. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-IEX-2017-11, and should be submitted on or before August 18, 2017.

V. Accelerated Approval of Proposed Rule Change, as Modified by Amendment No. 3

The Commission finds good cause to approve the proposed rule change, as modified by Amendment No. 3, prior to the thirtieth day after the date of publication of the notice of Amendment No. 3 in the **Federal Register**. The Commission believes that the proposed changes to the description of the process for determining the Opening Match Price that were included in Amendment No. 3 add clarity to the price determination process without materially changing the proposal from what the Exchange originally filed. Additionally, the Commission believes that the proposed addition of a rounding process for the Cross Tie Breaker to prevent certain Tick Size Pilot securities from trading in an impermissible increment eliminates a potential conflict between the Tick Size Pilot and the Opening Process. Moreover, the Commission believes that applying the rounding process to all non-IEX-listed securities will allow for consistent handling of securities in the Opening

Process and avoid introducing unnecessary technical complexities. The Commission does not believe that any of the changes proposed in Amendment No. 3 introduce novel concepts, but rather add detail to better reflect in the proposed rule text how the proposed Opening Process would work for non-IEX-listed securities, and also reconciles the proposed Opening Process with the tick-size requirements of the Tick Size Pilot. Accordingly, for the reasons noted above, the Commission finds good cause for approving the proposed rule change, as modified by Amendment No. 3, on an accelerated basis, pursuant to Section 19(b)(2) of the Act.⁶²

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,⁶³ that the proposed rule change (SR-IEX-2017-11), as modified by Amendment No. 3 thereto, be, and hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁶⁴

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017-15908 Filed 7-27-17; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-81193; File No. SR-MIAX-2017-35]

Self-Regulatory Organizations; Miami International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend MIAx Options Rules 404, 506, 806, and 1701

July 24, 2017.

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 July 19, 2017, Miami International Securities Exchange, LLC ("MIAx Options" or the "Exchange") filed with the Securities and Exchange Commission ("Commission") a 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

⁶² 15 U.S.C. 78s(b)(2).

⁶³ *Id.*

⁶⁴ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

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 make minor corrective changes to Exchange Rule 404, Series of Option Contracts Open for Trading; Rule 506, Collection and Dissemination of Quotations; Rule 806, Risk Analysis of Market Maker Accounts; and Rule 1701, Consolidated Audit Trail Compliance Rule—Definitions.

The text of the proposed rule change is available on the Exchange's Web site 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 the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Exchange Rules 404, Series of Option Contracts Open for Trading; Rule 506, Collection and Dissemination of Quotations; Rule 806, Risk Analysis of Market Maker Accounts; and Rule 1701, Consolidated Audit Trail Compliance Rule—Definitions to make minor non-substantive corrective changes.

First, the Exchange proposes to amend Exchange Rule 404, Series of Option Contracts Open for Trading, Interpretation and Policy .08, Mini Option Contracts, paragraph (a), to correct typographical errors in the last sentence. Currently, the sentence reads, "[m]ini-option contracts may currently be listed on SPDR S&P 500 (SPY), Apple, Inc. (AAPL), SPDR Gold Trust (GLD), Alphabet, Inc. (GOOGL) and Amazon.com Inc. (AMZN)." The commas should be removed from "Apple, Inc." and "Alphabet, Inc.," and a comma should be inserted in

"Amazon.com Inc." Therefore, the Exchange proposes to amend this Rule to correctly reflect the names of Apple Inc., Alphabet Inc., and Amazon.com, Inc.

Second, the Exchange proposes to amend Exchange Rule 404, Series of Option Contracts Open for Trading, Interpretation and Policy .08, Mini Option Contracts, paragraph (b), to correct typographical errors in the last sentence. Currently, the sentence reads, "[f]or example, a call series strike price to deliver 10 shares of stock at \$125 per share has a total deliverable value of \$1250, and the strike price will be set at 125." A comma should be inserted in the number "\$1250" and a dollar sign should be inserted before the number "125." Therefore, the Exchange proposes to amend this Rule to replace the number "\$1250" with "\$1,250" and replace the number "125" with "\$125."

Third, the Exchange proposes to amend Exchange Rule 506(c) to convert the Roman numeral list item identifiers to numerical identifiers to properly conform to the hierarchical heading scheme used throughout the Exchange's rulebook. Paragraphs (i) and (ii) are incorrectly numbered and should be numbered (1) and (2). Therefore, the Exchange proposes to amend this Rule to correctly number the paragraphs as (1) and (2).

Fourth, the Exchange proposes to amend Exchange Rule 806(b)(3) to correct a minor typographical error in the last word of this subparagraph. Currently, the section reads, "[o]ptions prices shall be estimated through use of recognized options pricing models such as, but not limited to, Black-Scholes and Cox-Reubenstein." The word "Cox-Reubenstein" is misspelled and the Exchange proposes to amend this Rule to correct the spelling to "Cox-Rubinstein."

Finally, the Exchange proposes to amend Exchange Rule 1701(d) to correct a typographical error. Currently, the section reads, ". . . required to be reported under the Compliance Audit Trail . . ." The word "Compliance" is incorrect and should be replaced with "Consolidated."

2. Statutory Basis

The Exchange believes that its proposed rule change is consistent with Section 6(b) of the Act³ in general, and furthers the objectives of Section 6(b)(5) of the Act⁴ in particular, in that they are 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 mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes the proposed changes promote just and equitable principles of trade and remove impediments to and perfect the mechanism of a free and open market and a national market system because the proposed rule change corrects minor typographical errors and corrects errors in the hierarchical heading scheme to provide uniformity in the Exchange's rulebook. The Exchange notes that the proposed changes to Exchange Rule 404, Series of Option Contracts Open for Trading; Rule 506, Collection and Dissemination of Quotations; Rule 806, Risk Analysis of Market Maker Accounts; and Rule 1701, Consolidated Audit Trail Compliance Rule—Definitions do not alter the application of each rule. As such, the proposed amendments would foster cooperation and coordination with persons engaged in facilitating transactions in securities and would remove impediments to and perfect the mechanism of a free and open market and a national exchange system. In particular, the Exchange believes that the proposed changes will provide greater clarity to Members⁵ and the public regarding the Exchange's Rules. It is in the public interest for rules to be accurate and concise so as to eliminate the potential for confusion.

B. Self-Regulatory Organization's Statement on Burden on Competition

MIAX Options 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 will have no impact on competition as they are not designed to address any competitive issues but rather are designed to add additional clarity to existing rules and to remedy minor non-substantive issues in the text of various rules identified in this proposal.

The Exchange does not believe that the proposed rule change will impose any burden on intermarket competition as the Rules apply equally to all Exchange Members.

⁵ 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.

³ 15 U.S.C. 78f(b).

⁴ 15 U.S.C. 78f(b)(5).

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

Pursuant to Section 19(b)(3)(A) of the Act⁶ and Rule 19b-4(f)(6)⁷ thereunder, the Exchange has designated this proposal as one that effects a change that: (i) Does not significantly affect the protection of investors or the public interest; (ii) does not impose any significant burden on competition; and (iii) by its terms, does not become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest.

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-MIAX-2017-35 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-2017-35. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use

only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-MIAX-2017-35, and should be submitted on or before August 18, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁸

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017-15906 Filed 7-27-17; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-81191; File No. SR-BatsBZX-2017-46]

Self-Regulatory Organizations; Bats BZX Exchange, Inc.; Notice of Filing of a Proposed Rule Change to Rule 14.11(c), Index Fund Shares, To List and Trade Shares of the Aptus Fortified Value ETF, a Series of ETF Series Solutions

July 24, 2017.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on July 10, 2017, Bats BZX Exchange, Inc. ("Exchange" or "BZX") 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 filed a proposal to list and trade shares of the Aptus Fortified Value ETF (the "Fund"), a series of ETF Series Solutions (the "Trust"), under Rule 14.11(c) ("Index Fund Shares").

The text of the proposed rule change is available at the Exchange's Web site at www.bats.com, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to list and trade the Shares under Rule 14.11(c)(3), which governs the listing and trading of Index Fund Shares on the Exchange.³ The Fund will be an index-based exchange traded fund ("ETF"). The Exchange is submitting this proposed rule change because the Index, as defined below, does not meet all of the "generic" listing requirements of Rule 14.11(c)(3)(A)(i), applicable to the listing of Index Fund Shares based upon an index of "U.S. Component Stocks."⁴ Specifically, Rule 14.11(c)(3)(A)(i) sets forth the requirements to be met by components of an index or portfolio of U.S. Component Stocks. Because the

³ The Commission originally approved BZX Rule 14.11(c) in Securities Exchange Act Release No. 65225 (August 30, 2011), 76 FR 55148 (September 6, 2011) (SR-BATS-2011-018).

⁴ As defined in Rule 14.11(c)(1)(D), the term "U.S. Component Stock" shall mean an equity security that is registered under Sections 12(b) or 12(g) of the Act, or an American Depositary receipt, the underlying equity security of which is registered under Sections 12(b) or 12(g) of the Act.

⁶ 15 U.S.C. 78s(b)(3)(A).

⁷ 17 CFR 240.19b-4(f)(6).

⁸ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

Index may purchase put options on a security that tracks the broader U.S. equity market, as further described below, which are not included in the definition of “U.S. Component Stocks” as defined in Rule 14.11(c)(1)(D), the Index does not satisfy the requirements of Rule 14.11(c)(3)(A)(i). The Index will otherwise conform to the initial and continued listing criteria under Rule 14.11(c). Rule 14.11(i), which covers the listing and trading of actively managed ETFs (“Managed Fund Shares”), does however provide generic listing standards related to funds holding listed derivatives in Rule 14.11(i)(4)(C)(iv), which includes the kinds of options that may be held by the Index. The Exchange believes that, while the Index wouldn’t necessarily meet the requirements of Rule 14.11(i)(4)(C)(iv), the listing and trading of the Shares would not give rise to the policy concerns on which the substance of Rule 14.11(i)(4)(C)(iv) is based, as further described below.

The Shares will be offered by the Trust, which was established as a Delaware statutory trust on February 9, 2012. The Trust is registered with the Commission as an open-end investment company and has filed a registration statement on behalf of the Fund on Form N-1A (“Registration Statement”) with the Commission.⁵

The Fund intends to qualify each year as a regulated investment company under Subchapter M of the Internal Revenue Code of 1986, as amended.

Aptus Fortified Value ETF

According to the Registration Statement, the Fund will seek to track the performance, before fees and expenses, of the Aptus Fortified Value Index (the “Index”). The Index is a rules-based, equal-weighted index that is designed to gain exposure to 50 of the most undervalued U.S.-listed common stocks and real estate investment trusts (“REITs”), while hedging against significant U.S. equity market declines when the market is overvalued.

The Index is composed of two components: An equity component of 50 common stocks and REITs and, when the Index determines that the U.S. equity market is overvalued, a “tail hedge” of long put options on a security that tracks the broader U.S. equity market.⁶ When the tail hedge is not in effect, the Index will be composed

100% of the equity component. At the time the tail hedge is implemented, the Index will be composed 99.5% of the equity component and 0.50% of the tail hedge, as described below.

When the tail hedge is implemented, the Index will reallocate 0.50% of its weight to buy put options on a large, highly liquid ETF that tracks the performance of the large-cap U.S. equity market (the “Underlying ETF”). The Underlying ETF will be the ETF that tracks the large-cap U.S. equity market and has the highest average daily options volume as determined annually by the Index rules. A put option gives the purchaser the right to sell shares of the underlying asset at a specified price (“strike price”) prior to a specified date (“expiration date”). The purchaser pays a cost (premium) to purchase the put option. In the event the underlying asset declines in value, the value of the put option will generally increase, and in the event the underlying asset appreciates in value, the put option may end up worthless and the premium may be lost.

At the time the tail hedge is implemented, the put options on the Underlying ETF will have an expiration date of approximately three months from the date the tail hedge is implemented, and the strike price will be approximately 30% less than the most recent closing price of the Underlying ETF.

On the last business day of each month, any options held by the Index are sold. If the tail hedge will not be in effect for the following month, the weight of such options, if any, will be reallocated pro rata to the securities in the Index’s equity component. If the tail hedge will continue in effect for the following month, the Index is rebalanced (*i.e.*, no equity securities are added or deleted) such that the tail hedge (with new options purchased) has a weight of 0.50% and the equity component securities are adjusted up or down pro rata to have a weight of 99.5%.⁷

⁷ This calculation is based on the cost to purchase the put contracts. While the Index would not necessarily meet the requirements of Rule 14.11(i)(4)(C)(iv)(b) applicable to options holdings for Managed Fund Shares, which prevents the aggregate gross notional value of listed derivatives based on any single underlying reference asset from exceeding 30% of the weight of the portfolio (including gross notional exposures) and the aggregate gross notional value of listed derivatives based on any five or fewer underlying reference assets from exceeding 65% of the weight of the portfolio (including gross notional exposures), the actual potential downside associated with purchased put contracts is limited to the cost of the contract. The Exchange believes that this, combined with the relatively small percentage of the Index’s exposure to options on the Underlying ETF and the

The Exchange represents that, except for the 0.50% options position that the Index might hold, the Index will satisfy, on an initial and continued listing basis, all of the generic listing standards under Rule 14.11(c)(3)(A)(i) and all other applicable requirements for Index Fund Shares under Rule 14.11(c), including, but not limited to, requirements relating to the dissemination of key information such as the Net Asset Value, the Intraday Indicative Value, rules governing the trading of equity securities, trading hours, trading halts, surveillance, and the information circular, as set forth in Exchange rules applicable to Index Fund Shares and the orders approving such rules. Moreover, all of the equity securities and options contracts held by the Index trade on markets that are a member of Intermarket Surveillance Group (“ISG”) or affiliated with a member of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.⁸ All statements and representations made in this filing regarding (a) the description of the portfolio, (b) limitations on portfolio holdings or reference assets, or (c) the applicability of Exchange rules shall constitute continued listing requirements for listing the Shares on the Exchange. The issuer has represented to the Exchange that it will advise the Exchange of any failure by the Fund or the Shares to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will surveil for compliance with the continued listing requirements. If the Fund or the Shares are not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under Exchange Rule 14.12.

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act⁹ in general and Section 6(b)(5) of the Act¹⁰ in particular in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of

liquidity in the options market for the Underlying ETF mitigates the concerns that Rule 14.11(i)(4)(C)(iv)(b) is intended to address and would prevent the Shares from being susceptible to manipulation.

⁸ For a list of the current members and affiliate members of ISG, see www.isgportal.com. The Exchange notes that not all components of the Disclosed Portfolio for the Fund may trade on markets that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

⁹ 15 U.S.C. 78f.

¹⁰ 15 U.S.C. 78f(b)(5).

⁵ See Registration Statement on Form N-1A for the Trust, dated June 8, 2017 (File Nos. 333-179562 and 811-22668). The descriptions of the Fund and the Shares contained herein are based, in part, on information in the Registration Statement.

⁶ The Exchange notes that the equity component of the Index meets the requirements of Rule 14.11(c)(3)(A)(i).

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 proposed rule change 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 in that the Shares will meet each of the initial and continued listing criteria in BZX Rule 14.11(c) with the exception of the possible 0.50% of assets used to purchase put options.¹¹ While the Index would not necessarily meet the requirements of Rule 14.11(i)(4)(C)(iv)(b) applicable to options holdings for Managed Fund Shares, which prevents the aggregate gross notional value of listed derivatives based on any single underlying reference asset from exceeding 30% of the weight of the portfolio (including gross notional exposures) and the aggregate gross notional value of listed derivatives based on any five or fewer underlying reference assets from exceeding 65% of the weight of the portfolio (including gross notional exposures), the actual potential downside associated with purchased put contracts is limited to the cost of the contract. The Exchange believes that this, combined with the relatively small percentage of the Index's exposure to options on the Underlying ETF and the liquidity in the options market for the Underlying ETF mitigates the concerns that Rule 14.11(i)(4)(C)(iv)(b) is intended to address and would prevent the Shares from being susceptible to manipulation. The Exchange believes that its surveillance procedures are adequate to properly monitor the trading of the Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities

laws. All of the futures contracts held by the Fund will trade on markets that are a member of ISG or affiliated with a member of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. The Exchange may obtain information regarding trading in the Shares and the underlying equities and options contracts held by the Fund via the ISG from other exchanges who are members or affiliates of the ISG or with which the Exchange has entered into a comprehensive surveillance sharing agreement.¹² The Exchange further notes that the Fund will meet and be subject to all other requirements of Rule 14.11(c) and other applicable continued [sic] Net Asset Value, the Intraday Indicative Value, rules governing the trading of equity securities, trading hours, trading halts, surveillance, and the information circular, as set forth in Exchange rules applicable to Index Fund Shares and the orders approving such rules.

For the above reasons, the Exchange believes that the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act.

(B) Self-Regulatory Organization's Statement on Burden on Competition

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 purpose of the Act. The Exchange notes that the proposed rule change, rather will facilitate the listing and trading of an additional exchange-traded product that will enhance competition among both market participants and listing venues, to the benefit of investors and the marketplace.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposal 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-BatsBZX-2017-46 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090.

All submissions should refer to File No. SR-BatsBZX-2017-46. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR-BatsBZX-2017-46 and should be submitted on or before August 18, 2017.

¹¹ As noted above, the Exchange is proposing that the Fund be exempt from the requirement of Rule 14.11(i)(4)(C)(iv)(b) that prevents the aggregate gross notional value of listed derivatives based on any single underlying reference asset from exceeding 30% of the weight of the portfolio (including gross notional exposures) and the aggregate gross notional value of listed derivatives based on any five or fewer underlying reference assets from exceeding 65% of the weight of the portfolio (including gross notional exposures).

¹² See note 11, *supra*.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹³

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017-15904 Filed 7-27-17; 8:45 am]

BILLING CODE 8011-01-P

DEPARTMENT OF STATE

[Public Notice: 10066]

30-Day Notice of Proposed Information Collection: Refugee Biographic Data

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: The Department of State has submitted the information collection described below to the Office of Management and Budget (OMB) for approval. In accordance with the Paperwork Reduction Act of 1995 we are requesting comments on this collection from all interested individuals and organizations. The purpose of this Notice is to allow 30 days for public comment.

DATES: Submit comments directly to the Office of Management and Budget (OMB) up to August 28, 2017.

ADDRESSES: Direct comments to the Department of State Desk Officer in the Office of Information and Regulatory Affairs at the Office of Management and Budget (OMB). You may submit comments by the following methods:

- *Email:* oira_submission@omb.eop.gov. You must include the DS form number, information collection title, and the OMB control number in the subject line of your message.
- *Fax:* 202-395-5806. Attention: Desk Officer for Department of State.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for supporting documents, to Delicia Spruell, PRM/Admissions, 2025 E Street NW., SA-9, 8th Floor, Washington, DC 20522-0908.

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Refugee Biographic Data.
- *OMB Control Number:* 1405-0102.
- *Type of Request:* Extension of a Currently Approved Collection.
- *Originating Office:* Bureau of Population, Refugees, and Migration, Office of Admissions, PRM/A.
- *Form Number:* None.
- *Respondents:* Refugee applicants for the U.S. Refugee Admissions Program.

- *Estimated Number of Respondents:* 50,000.
- *Estimated Number of Responses:* 50,000.
- *Average Time per Response:* 30 minutes.
- *Total Estimated Burden Time:* 25,000 hours.
- *Frequency:* Once per respondent.
- *Obligation to Respond:* Require to Obtain a Benefit.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

The Refugee Biographic Data Sheet describes a refugee applicant's personal characteristics and is needed to match the refugee with a sponsoring voluntary agency for initial reception and placement in the United States under the U.S. Refugee Admissions Program administered by the Bureau of Population, Refugees, and Migration, as authorized by the Immigration and Nationality Act and the Refugee Act of 1980.

Methodology

Biographic information is collected in a face-to-face intake process with the applicant overseas. An employee of a Resettlement Support Center, under cooperative agreement with PRM, collects the information and enters it into the Worldwide Refugee Admissions Processing System.

Lawrence Bartlett,

Director, Office of Admissions, Bureau of Population, Refugees, and Migration, Department of State.

[FR Doc. 2017-15959 Filed 7-27-17; 8:45 am]

BILLING CODE 4710-33-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Membership in the National Parks Overflights Advisory Group

AGENCY: Federal Aviation Administration, Transportation.

ACTION: Solicitation of applications.

SUMMARY: The Federal Aviation Administration (FAA) and the National Park Service (NPS) are inviting interested persons to apply to fill three current openings on the National Parks Overflights Advisory Group (NPOAG). The openings represent environmental interests. The selected members will serve 3-year terms.

DATES: Persons interested in applying for the NPOAG openings representing environmental interests need to apply by August 25, 2017.

ADDRESSES: You may submit your interest in filling one of the NPOAG openings by either of the following methods:

- *Email:* Keith.Lusk@faa.gov.
- *Mail:* Keith Lusk, Federal Aviation Administration, Western-Pacific Region Headquarters, 15000 Aviation Boulevard, Lawndale, CA 90261.

FOR FURTHER INFORMATION CONTACT: Keith Lusk, Special Programs Staff, Federal Aviation Administration, Western-Pacific Region Headquarters, 15000 Aviation Boulevard, Lawndale, CA 90261, telephone: (310) 725-3808, email: Keith.Lusk@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

The National Parks Air Tour Management Act of 2000 (the Act) was enacted on April 5, 2000, as Public Law 106-181. The Act required the establishment of the advisory group within 1 year after its enactment. The NPOAG was established in March 2001. The advisory group is comprised of a balanced group of representatives of general aviation, commercial air tour operations, environmental concerns, and Native American tribes. The Administrator of the FAA and the Director of NPS (or their designees) serve as ex officio members of the group. Representatives of the Administrator and Director serve alternating 1-year terms as chairman of the advisory group.

In accordance with the Act, the advisory group provides "advice, information, and recommendations to the Administrator and the Director—

(1) On the implementation of this title [the Act] and the amendments made by this title;

¹³ 17 CFR 200.30-3(a)(12).

(2) On commonly accepted quiet aircraft technology for use in commercial air tour operations over a national park or tribal lands, which will receive preferential treatment in a given air tour management plan;

(3) On other measures that might be taken to accommodate the interests of visitors to national parks; and

(4) At the request of the Administrator and the Director, safety, environmental, and other issues related to commercial air tour operations over a national park or tribal lands.”

Membership

The NPOAG is made up of one member representing general aviation, three members representing the commercial air tour industry, four members representing environmental concerns, and two members representing Native American interests. Current members of the NPOAG are as follows:

The current NPOAG consists of Melissa Rudinger representing general aviation; Alan Stephen, Mark Francis, and Matthew Zuccaro representing commercial air tour operators; Rob Smith representing environmental interests with three current openings; and Leigh Kuwanwisiwma and Martin Begaye representing Native American interests.

Selection

In order to retain balance within the NPOAG, the FAA and NPS are seeking candidates interested in filling these three open seats representing environmental interests. The FAA and NPS invite persons interested in representing environmental interests on the NPOAG to contact Mr. Keith Lusk (contact information is written above in **FOR FURTHER INFORMATION CONTACT**). Requests to serve on the NPOAG must be made to Mr. Lusk in writing and postmarked or emailed on or before August 25, 2017. The request should indicate whether or not you are a member of an environmental association or group. The request should also state what expertise you would bring to the NPOAG as related to issues and concerns with aircraft flights over national parks. The term of service for NPOAG members is 3 years. Current members may re-apply for another term.

On June 18, 2010, President Obama signed a Presidential Memorandum directing agencies in the Executive Branch not to appoint or re-appoint federally registered lobbyists to advisory committees and other boards and commissions. Therefore, before appointing an applicant to serve on the NPOAG, the FAA and NPS will require

the prospective candidate to certify that they are not a federally registered lobbyist.

Issued in Hawthorne, CA, on July 18, 2017.

Keith Lusk,

Program Manager, Special Programs Staff, Western-Pacific Region.

[FR Doc. 2017-15489 Filed 7-27-17; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE-2017-62]

Petition for Exemption; Summary of Petition Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of the FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number involved and must be received on or before August 17, 2017.

ADDRESSES: Send comments identified by docket number FAA-2017-0683 using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and follow the online instructions for sending your comments electronically.

- *Mail:* Send comments to Docket Operations, M-30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12-140, West Building Ground Floor, Washington, DC 20590-0001.

- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

- *Fax:* Fax comments to Docket Operations at 202-493-2251.

Privacy: 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>.

Docket: Background documents or comments received may be read at <http://www.regulations.gov> at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lynette Mitterer, ANM-113, Federal Aviation Administration, 1601 Lind Avenue SW., Renton, WA 98057-3356, email Lynette.Mitterer@faa.gov, phone (425) 227-1047; or Alphonso Pendergrass, ARM-200, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591, email alphonso.pendergrass@faa.gov, phone (202) 267-4713.

This notice is published pursuant to 14 CFR 11.85.

Victor Wicklund,

Manager, Transport Standards Staff.

Petition for Exemption

Docket No.: FAA-2017-0683.

Petitioner: The Boeing Company.

Section of 14 CFR Affected:

§ 25.813(e).

Description of Relief Sought: The petitioner seeks an exemption from 14 CFR 25.813(e), amendment 25-128, doors between passenger compartments, for the purpose of installing high-wall suites in the premium cabin of Boeing Model 777-9 airplanes.

[FR Doc. 2017-15918 Filed 7-27-17; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on MoPac (Loop 1) Intersections, Travis County, Texas

AGENCY: Federal Highway Administration (FHWA), U.S. DOT

ACTION: Notice of limitation on claims for judicial review of actions by TxDOT and Federal agencies.

SUMMARY: On February 19, 2016, the Texas Department of Transportation (TxDOT) issued a notice for the approval of the Final Environmental Assessment (Final EA) and the Finding of No Significant Impact (FONSI) for the proposed highway project, MoPac (Loop

1) Intersections from North of Slaughter Lane to South of La Crosse Avenue in Travis County, Texas. This notice applies solely to actions by TxDOT and Federal agencies which occurred subsequent to the publication of the prior notice and does not apply to actions addressed in the prior notice.

DATES: By this notice, TxDOT is advising the public of final agency actions subject to 23 U.S.C. 139(l)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before December 26, 2017. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: Mr. Carlos Swonke, Environmental Affairs Division, Texas Department of Transportation, 125 East 11th Street, Austin, Texas 78701; telephone: (512) 416-2734; email: carlos.swonke@txdot.gov. TxDOT's normal business hours are 8:00 a.m. to 5:00 p.m. (central time), Monday through Friday.

SUPPLEMENTARY INFORMATION: Notice is hereby given that TxDOT and Federal agencies have taken final agency actions by issuing licenses, permits, and approvals regarding the following highway project in the State of Texas: MoPac (Loop 1) Intersections, Travis County, Texas.

This notice announces the following actions relating to the proposed Loop 1 Intersections project taken by TxDOT and Federal agencies which occurred subsequent to the publication of the prior notice and that are final within the meaning of 23 U.S.C. 139(l)(1): TxDOT's reevaluation of the Loop 1 Intersections project (Reevaluation); and TxDOT's effect determination and conclusion of informal consultation with U.S. Fish and Wildlife Service (USFWS) pursuant to Section 7 of the Endangered Species Act. Those actions grant licenses, permits, and approvals for the project.

Subsequent to completion of the Final EA and FONSI in December 2015 and issuance of the prior notice on February 19, 2016, TxDOT performed a Reevaluation to examine the potential effects of the proposed Loop 1 Intersections project on the golden-cheeked warbler (GCW) (*Setophaga chrysoparia*), Austin blind salamander (ABS) (*Eurycea waterlooensis*), Barton Springs salamander (BSS) (*Eurycea sosorum*), and designated critical habitat for the ABS. In the Reevaluation, TxDOT concluded that the Loop 1 Intersections project may affect but is not likely to adversely affect the GCW,

ABS, and BSS and that the project would result in no adverse modification of designated critical habitat for the ABS. Further, TxDOT determined that a Supplemental Environmental Assessment was not necessary.

Pursuant to the Endangered Species Act, 16 U.S.C. 1531-1544, USFWS issued its concurrence with TxDOT's determination that the Loop 1 Intersections project may affect but is not likely to adversely affect the GCW, ABS, and BSS and that the project would result in no adverse modification of designated critical habitat for the ABS.

The actions by TxDOT and the Federal agencies, and the laws under which such actions were taken, are described in the Reevaluation, signed on June 28, 2017, and in the USFWS concurrence letter issued on June 23, 2017. The Reevaluation, USFWS concurrence letter, and other documents in the administrative record file are available by contacting TxDOT at the address provided above.

This notice applies to all TxDOT decisions and Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. *General:* National Environmental Policy Act (NEPA) [42 U.S.C. 4321-4351]; Federal-Aid Highway Act [23 U.S.C. 109].

2. *Air:* Clean Air Act [42 U.S.C. 7401-7671(q)].

3. *Land:* Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303]; Landscaping and Scenic Enhancement (Wildflowers), 23 U.S.C. 319.

4. *Wildlife:* Endangered Species Act [16 U.S.C. 1531-1544 and Section 1536]; Fish and Wildlife Coordination Act [16 U.S.C. 661-667(d)]; Migratory Bird Treaty Act [16 U.S.C. 703-712].

5. *Historic and Cultural Resources:* Section 106 of the National Historic Preservation Act of 1966, as amended [16 U.S.C. 470(f) *et seq.*]; Archeological Resources Protection Act of 1977 [16 U.S.C. 470(aa)-11]; Archeological and Historic Preservation Act [16 U.S.C. 469-469(c)]; Native American Grave Protection and Repatriation Act (NAGPRA) [25 U.S.C. 3001-3013].

6. *Social and Economic:* Civil Rights Act of 1964 [42 U.S.C. 2000(d)-2000(d)(1)]; American Indian Religious Freedom Act [42 U.S.C. 1996]; Farmland Protection Policy Act (FPPA) [7 U.S.C. 4201-4209].

7. *Wetlands and Water Resources:* Clean Water Act [33 U.S.C. 1251-1377]; Land and Water Conservation Fund (LWCF) [16 U.S.C. 4601-4604]; Safe Drinking Water Act (SDWA) [42 U.S.C.

300(f)-300(j)(6)]; Rivers and Harbors Act of 1899 [33 U.S.C. 401-406]; Wild and Scenic Rivers Act [16 U.S.C. 1271-1287]; Emergency Wetlands Resources Act [16 U.S.C. 3921, 3931]; TEA-21 Wetlands Mitigation [23 U.S.C. 103(b)(6)(m), 133(b)(11)]; Flood Disaster Protection Act [42 U.S.C. 4001-4128].

8. *Executive Orders:* E.O. 11990, Protection of Wetlands; E.O. 11988, Floodplain Management; E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations; E.O. 11593, Protection and Enhancement of Cultural Resources; E.O. 13007, Indian Sacred Sites; E.O. 13287, Preserve America; E.O. 13175, Consultation and Coordination with Indian Tribal Governments; E.O. 11514, Protection and Enhancement of Environmental Quality; E.O. 13112, Invasive Species; E.O. 12372, Intergovernmental Review of Federal Programs.

The environmental review, consultation, and other actions required by applicable Federal environmental laws for this project are being, or have been, carried out by TxDOT pursuant to 23 U.S.C. 327 and a Memorandum of Understanding dated December 16, 2014, and executed by FHWA and TxDOT.

Authority: 23 U.S.C. 139(l)(1).

Issued on: July 11, 2017.

Michael T. Leary,

Director, Planning and Program Development, Federal Highway Administration.

[FR Doc. 2017-15030 Filed 7-27-17; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA-2017-0033]

Agency Information Collection Activities: Request for Comments for a New Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice and request for comments.

SUMMARY: The FHWA has forwarded the information collection request described in this notice to the Office of Management and Budget (OMB) for approval of a new information collection. We published a **Federal Register** Notice with a 60-day public comment period on this information collection on May 17, 2017. We are required to publish this notice in the

Federal Register by the Paperwork Reduction Act of 1995.

DATES: Please submit comments by August 28, 2017.

ADDRESSES: You may send comments within 30 days to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503, Attention DOT Desk Officer. You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FHWA's performance; (2) the accuracy of the estimated burden; (3) ways for the FHWA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, without reducing the quality of the collected information. All comments should include the Docket No. FHWA-2017-0033.

FOR FURTHER INFORMATION CONTACT: Esther Strawder, 202-366-6836, Office of Safety, Federal Highway Administration, Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590. Office hours are from: 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Title: Roadway Safety Data Capability Assessment.

Background: Federal Highway Administration (FHWA) is initiating a large-scale effort to expand its relationships with the States to develop a better understanding of their data capabilities and conditions of data collection. The effort, known as the Roadway Safety Data Capabilities Assessment, will be conducted in 50 States, the District of Columbia and Puerto Rico. The two major objectives are to (1) create a mechanism by which a national and State-specific gap analyses could be conducted to identify opportunities to improve capabilities and (2) provide tools and assistance to assist States in overcoming those gaps. The results will provide a detailed understanding (for FHWA and the States themselves) of the needs for complete, accurate roadway, crash, and traffic volume data for use in safety analysis. The assessment will yield both a quantitative understanding of each State's capability (using a capability maturity model) and State-specific action plans in the key areas of:

- Roadway inventory data collection and technical standards
- Data analysis tools and uses
- Data management and governance
- Data integration and expandability

- Performance management
- The results will also be useful for States and FHWA in their efforts to develop programs and make improvements in roadway safety management.

Respondents: 50 State DOT participants the District of Columbia and Puerto Rico.

Frequency: Once every 5 years.

Estimated Average Burden per Response: Approximately 36 hours per participant over a year.

Estimated Total Annual Burden Hours: Approximately 1,728 hours.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection of information is necessary for the U.S. DOT's performance, including whether the information will have practical utility; (2) the accuracy of the U.S. DOT's estimate of the burden of the proposed information collection; (3) ways to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.48.

Issued On: July 24, 2017.

Michael Howell,
Information Collection Officer.

[FR Doc. 2017-15940 Filed 7-27-17; 8:45 am]

BILLING CODE 4910-22-P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[FTA Docket No. FTA 2017-0020]

Agency Information Collection Activity Under OMB Review

AGENCY: Federal Transit Administration, DOT.

ACTION: Notice of request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Requirements (ICRs) abstracted below have been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describe the nature of the information collection and their expected burdens. The **Federal Register** notice with a 60-day comment period

soliciting comments on the following collections of information was published on April 24, 2017 (82 FR 18964).

DATES: Comments must be submitted on or before August 28, 2017.

FOR FURTHER INFORMATION CONTACT: Tia Swain, Office of Administration, Management Planning Division, 1200 New Jersey Avenue SE., Mail Stop TAD-10, Washington, DC 20590 (202) 366-0354 or tia.swain@dot.gov.

SUPPLEMENTARY INFORMATION: The Paperwork Reduction Act of 1995 (PRA), Public Law 104-13, Section 2, 109 Stat. 163 (1995) (codified as revised at 44 U.S.C. 3501-3520), and its implementing regulations, 5 CFR part 1320, require Federal agencies to issue two notices seeking public comment on information collection activities before OMB may approve paperwork packages. 44 U.S.C. 3506, 3507; 5 CFR 1320.5, 1320.8(d)(1), 1320.12. On April 24, 2017, FTA published a 60-day notice (82 FR 18964) in the **Federal Register** soliciting comments on the ICR that the agency was seeking OMB approval. FTA received no comments after issuing this 60-day notice. Accordingly, DOT announces that these information collection activities have been re-evaluated and certified under 5 CFR 1320.5(a) and forwarded to OMB for review and approval pursuant to 5 CFR 1320.12(c).

Before OMB decides whether to approve these proposed collections of information, it must provide 30 days for public comment. 44 U.S.C. 3507(b); 5 CFR 1320.12(d). Federal law requires OMB to approve or disapprove paperwork packages between 30 and 60 days after the 30-day notice is published. 44 U.S.C. 3507 (b)-(c); 5 CFR 1320.12(d); *see also* 60 FR 44978, 44983, Aug. 29, 1995. OMB believes that the 30-day notice informs the regulated community to file relevant comments and affords the agency adequate time to digest public comments before it renders a decision. 60 FR 44983, Aug. 29, 1995. Therefore, respondents should submit their respective comments to OMB within 30 days of publication to best ensure having their full effect. 5 CFR 1320.12(c); *see also* 60 FR 44983, Aug. 29, 1995.

The summaries below describe the nature of the information collection requirements (ICRs) and the expected burden. The requirements are being submitted for clearance by OMB as required by the PRA.

Title: Charter Service Operations.
OMB Control Number: 2132-0543.

Type of Request: Revision of a currently approved information collection.

Abstract: FTA recipients may only provide charter bus service with FTA-funded facilities and equipment if the charter service is incidental to the provision of transit service (49 U.S.C. 5323(d)). This restriction protects charter service providers from unauthorized competition by FTA recipients.

The requirements of 49 U.S.C. 5323(d) are implemented in FTA's charter regulation (Charter Service Rule) at 49 CFR part 604. Amended in 2008, the Charter Service Rule now contains five (5) provisions that impose information collection requirements on FTA recipients of financial assistance from FTA under Federal Transit Law.

First, 49 CFR 604.4 requires all applicants for Federal financial assistance under Federal Transit Law, unless otherwise exempted under 49 CFR 604.2, to enter into a "Charter Service Agreement," contained in the Certifications and Assurances for FTA Assistance Programs. The Certifications and Assurances become a part of the Grant Agreement or Cooperative Agreement for Federal financial assistance upon receipt of Federal funds. The rule requires each applicant to submit one Charter Service Agreement for each year that the applicant intends to apply for the Federal financial assistance specified above.

Second, 49 CFR 604.14(3) requires a recipient of Federal funds under Federal Transit Law, unless otherwise exempt, to provide email notification to all registered charter providers in the recipient's geographic service area each time the recipient receives a request for charter service that the recipient is interested in providing.

Third, 49 CFR 604.12(c) requires a recipient, unless otherwise exempt under 49 CFR part 604.2, to submit on a quarterly basis records of all instances that the recipient provided charter service.

Fourth, 49 CFR 604.13 requires a private charter provider to register on FTA's Charter Registration Web site at <http://ftawebprod.fta.dot.gov/CharterRegistration/> in order to qualify as a registered charter service provider and receive email notifications by recipients that are interested in providing a requested charter service. The rule requires that a registered charter service provider must update its information on the Charter Registration Web site at least once every two years. Currently, there are a total of 227 registered private charter service providers.

Lastly, 49 CFR 604.7 permits recipients to provide charter service to Qualified Human Service Organizations (QHSO) under limited circumstances. QHSOs that do not receive Federal funding under programs listed in Appendix A to Part 604 and seek to receive free or reduced rate services from recipients must register on FTA's Charter Registration Web site (49 CFR 604.15(a)).

Respondents: State and local government, business or other for-profit institutions, and non-profit institutions.

Estimated Annual Burden on Respondents: .05 hours for each of the 955 Recipient respondents under 49 CFR 604.4, 1.25 hours for each of the 114 Recipient respondents under 49 CFR 604.12, 0.50 hours for each of the 114 Recipient respondents under 49 CFR 604.14, 0.50 hours for each of the 59 non-profit respondents, and 0.50 hours for each of the estimated 227 for-profit respondents.

Estimated Total Annual Burden: 390.5 hours.

Frequency: Annually, bi-annually, quarterly, and as required.

ADDRESSES: All written comments must refer to the docket number that appears at the top of this document and be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503, Attention: FTA Desk Officer. Alternatively, comments may be sent via email to the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget, at the following address: oira_submissions@omb.eop.gov.

Comments are Invited On: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this notice in the **Federal Register**.

William Hyre,
Deputy Associate Administrator for Administration.

[FR Doc. 2017-15921 Filed 7-27-17; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The public is invited to submit comments on these requests.

DATES: Comments should be received on or before August 28, 2017 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at OIRA_Submission@OMB.EOP.gov and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8142, Washington, DC 20220, or email at PRA@treasury.gov.

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained from Jennifer Leonard by emailing PRA@treasury.gov, calling (202) 622-0489, or viewing the entire information collection request at www.reginfo.gov.

SUPPLEMENTARY INFORMATION:

Bureau of the Fiscal Service (FS)

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

OMB Control Number: 1530-0023.

Type of Review: Extension without change of a currently approved collection.

Abstract: This collection of information is necessary to enable the Agency to garner customer and stakeholder feedback in an efficient, timely manner, in accordance with our commitment to improving service delivery. The information collected from our customers and stakeholders will help ensure that users have an effective, efficient, and satisfying experience with the Agency's programs.

Form: None.
Affected Public: Individuals and households.
Estimated Total Annual Burden Hours: 10,000.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: July 25, 2017.

Spencer W. Clark,

Treasury PRA Clearance Officer.

[FR Doc. 2017-15976 Filed 7-27-17; 8:45 am]

BILLING CODE 4810-AS-P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Multiple Internal Revenue Service Information Collection Requests

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The public is invited to submit comments on these requests.

DATES: Comments should be received on or before August 28, 2017 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at OIRA_Submission@OMB.EOP.gov and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8142, Washington, DC 20220, or email at PRA@treasury.gov.

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained from Jennifer Leonard by emailing PRA@treasury.gov, calling (202) 622-0489, or viewing the entire information collection request at www.reginfo.gov.

SUPPLEMENTARY INFORMATION:

Internal Revenue Service (IRS)

Title: United States Gift (and Generation-Skipping Transfer) Tax Return.

OMB Control Number: 1545-0020.

Type of Review: Revision of a currently approved collection.

Abstract: Form 709 is used by individuals to report transfers subject to the gift and generation-skipping transfer taxes and to compute these taxes. IRS uses the information to enforce these taxes and to compute the estate tax.

Form: IRS Form 709.

Affected Public: Individuals and households.

Estimated Total Annual Burden Hours: 1,726,700.

Title: Employer's Quarterly Federal Tax Return.

OMB Control Number: 1545-0029.

Type of Review: Revision of a currently approved collection.

Abstract: Form 941 is used by employers to report payments made to employees subject to income and social security/Medicare taxes and the amounts of these taxes. Form 941-PR is used by employers in Puerto Rico to report social security and Medicare taxes only. Form 941-SS is used by employers in the U.S. possessions to report social security and Medicare taxes only. Schedule B is used by employers to record their employment tax liability. The Form 8974 was developed to determine the portion of the elected amount that can be claimed for the quarter on the Form 941.

Form: IRS Forms 941 and 8974.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 402,024,858.

Title: Proceeds From Broker and Barter Exchange Transactions.

OMB Control Number: 1545-0715.

Type of Review: Revision of a currently approved collection.

Abstract: Form 1099-B is used by brokers and barter exchanges to report proceeds from transactions to the Internal Revenue Service. The form will be used by IRS to verify compliance with the reporting rules and to verify that the recipient has included the proper amount of income on his or her return.

Form: IRS Form 1099-B.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 674,360,608.

Title: Mortgage Interest Statement.

OMB Control Number: 1545-0901.

Type of Review: Revision of a currently approved collection.

Abstract: Form 1098 is used to report \$600 or more of mortgage interest received from an individual in the course of the mortgagor's trade or business.

Form: IRS Form 1098.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 17,849,114.

Title: Substitute Mortality Tables for Single Employer Defined Benefit Plans.
OMB Control Number: 1545-2073.

Type of Review: Revision of a currently approved collection.

Abstract: Revenue Procedure 2007-37 has been updated (*i.e.*, in effect, superseded) by Revenue Procedure 2008-62, 2008-42 IRB 935. Revenue Procedure 2007-37 may be relied on only for requests submitted prior to December 1, 2008. This revenue procedure describes the process for obtaining a letter ruling as to the acceptability of substitute mortality tables under section 430(h)(3)(C) of the Code.

Form: None.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 60,000.

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

OMB Control Number: 1545-2208.

Type of Review: Revision of a currently approved collection.

Abstract: This collection of information is necessary to enable the Agency to garner customer and stakeholder feedback in an efficient, timely manner, in accordance with our commitment to improving service delivery. The information collected from our customers and stakeholders will help ensure that users have an effective, efficient, and satisfying experience with the Agency's programs.

Form: None.

Affected Public: Individuals and households.

Estimated Total Annual Burden Hours: 15,000.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: July 25, 2017.

Spencer W. Clark,

Treasury PRA Clearance Officer.

[FR Doc. 2017-15977 Filed 7-27-17; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Multiple Departmental Offices Information Collection Requests

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury will submit the following

information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The public is invited to submit comments on these requests.

DATES: Comments should be received on or before August 28, 2017 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at OIRA_Submission@OMB.EOP.gov and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8142, Washington, DC 20220, or email at PRA@treasury.gov.

FOR FURTHER INFORMATION CONTACT:

Copies of the submissions may be obtained from Jennifer Leonard by emailing PRA@treasury.gov, calling (202) 622-0489, or viewing the entire information collection request at www.reginfo.gov.

SUPPLEMENTARY INFORMATION:

Departmental Offices (DO)

Title: Treasury International Capital Form S, "Purchases and Sales of Long-term Securities by Foreign-Residents".

OMB Control Number: 1505-0001.

Type of Review: Revision of a currently approved collection.

Abstract: Form S is required by law and is designed to collect timely information on international portfolio capital movements, including foreign-residents' purchases and sales of long-term securities in transactions with U.S. persons. The information is important to key components of the U.S. balance of payments accounts and international investment position, as well as in the formulation of U.S. international financial and monetary policies.

Form: Form S.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 17,346.

Title: Troubled Asset Relief Program—Conflicts of Interest.

OMB Control Number: 1505-0209.

Type of Review: Extension without change of a currently approved collection.

Abstract: Authorized under the Emergency Economic Stabilization Act (EESA) of 2008 (Pub. L. 110-343), as amended by the American Recovery and

Reinvestment Act (ARRA) of 2009, the Department of the Treasury has implemented aspects of the Troubled Asset Relief Program (TARP) by codifying section 108 of EESA. Title 31 CFR part 31, TARP Conflict of Interest, sets forth the process for reviewing and addressing actual or potential conflicts of interest among any individuals or entities seeking or having a contract or financial agency agreement with the Treasury for services under EESA. The information collection required by this part will be used to evaluate and minimize real and apparent conflicts of interest related to contractual or financial agent agreement services performed under TARP.

Form: None.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 572.

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

OMB Control Number: 1505-0231.

Type of Review: Extension without change of a currently approved collection.

Abstract: This collection of information is necessary to enable the Agency to garner customer and stakeholder feedback in an efficient, timely manner, in accordance with our commitment to improving service delivery. The information collected from our customers and stakeholders will help ensure that users have an effective, efficient, and satisfying experience with the Agency's programs.

Form: None.

Affected Public: Individuals and households.

Estimated Total Annual Burden Hours: 3,500.

Authority: 44 U.S.C. 3501 et seq.

Dated: July 25, 2017.

Spencer W. Clark,

Treasury PRA Clearance Officer.

[FR Doc. 2017-15974 Filed 7-27-17; 8:45 am]

BILLING CODE 4810-25-P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Multiple Alcohol and Tobacco Tax and Trade Bureau Information Collection Requests

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury will submit the following

information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The public is invited to submit comments on these requests.

DATES: Comments should be received on or before August 28, 2017 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at OIRA_Submission@OMB.EOP.gov and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8142, Washington, DC 20220, or email at PRA@treasury.gov.

FOR FURTHER INFORMATION CONTACT:

Copies of the submissions may be obtained from Jennifer Leonard by emailing PRA@treasury.gov, calling (202) 622-0489, or viewing the entire information collection request at www.reginfo.gov.

SUPPLEMENTARY INFORMATION:

Alcohol and Tobacco Tax and Trade Bureau (TTB)

Title: Notice of Release of Tobacco Products, Cigarette Papers, or Cigarette Tubes.

OMB Control Number: 1513-0025.

Type of Review: Revision of a currently approved collection.

Abstract: The Internal Revenue Code (IRC) at 26 U.S.C. 5704 provides for, among other things, the release of imported or returned tobacco products and cigarette papers and tubes from customs custody, without payment of tax, for delivery to an export warehouse proprietor or a manufacturer of tobacco products or cigarette papers and tubes, in accordance with regulations issued by the Secretary of the Treasury. TTB F 5200.11 is used at importation by industry members, TTB, and customs bonded warehouse proprietors or government officials to, respectively, request, authorize, and document the release of tobacco products and cigarette papers and tubes from customs custody, without payment of tax, to a manufacturer or export warehouse proprietor authorized to receive such articles. (TTB F 5200.11 is used by industry members who do not file their entry information electronically through ACE, since those industry members filing electronically submit the relevant

information as data elements through ACE. The submission of information through ACE is captured under OMB Number 1513–0064.)

Form: TTB Form 5200.11

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 40.

Title: Distilled Spirits Plants—Notices of Alternations and Changes in Production Status, and Alternating Premises Records.

OMB Control Number: 1513–0044.

Type of Review: Revision of a currently approved collection.

Abstract: Under the Internal Revenue Code (IRC) at 26 U.S.C. 5178(a), a distilled spirits plant (DSP) is a delineated place on which only certain authorized activities may be conducted. However, under section 5178(b), the Secretary of the Treasury may authorize other businesses on a DSP's premises upon application under certain circumstances. Also, under the IRC at 26 U.S.C. 5221, DSP proprietors are required give written notification, in the form and manner prescribed by regulation, when they begin, suspend, or resume production of spirits. In addition, the IRC at 26 U.S.C. 5555 requires those liable for any tax imposed by chapter 51 of the IRC to keep such records, submit such returns and statements, and comply with such rules and regulations as the Secretary may prescribe. Under these authorities, TTB has issued regulations in 27 CFR part 19 requiring DSP proprietors to provide written notification regarding alternations of DSPs between proprietors or for customs purposes, and regarding changes to the production status of spirits. TTB also has issued regulations requiring DSP proprietors to keep alternating premises records when alternating operations at DSPs, including with an adjacent bonded wine cellar, taxpaid wine bottling house or brewery, as a manufacturer of eligible flavors, or as general premises.

Form: None.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 3,125.

Title: Special Tax “Renewal” Registration and Return/Special Tax Location Registration Listing.

OMB Control Number: 1513–0113.

Type of Review: Revision of a currently approved collection.

Abstract: The Internal Revenue Code at 26 U.S.C. 5731 and 5732 requires manufacturers of tobacco products, manufacturers of cigarette papers and tubes, and export warehouse proprietors

to pay an annual special (occupational) tax for each such premises that they operate. The IRC at 26 U.S.C. 5732 requires such taxes to be paid on the basis on a return under regulations issued by the Secretary of the Treasury. Form TTB F 5630.5R, which TTB sends out annually to tobacco industry members that have previously paid the special tax, meets this purpose. Use of TTB F 5630.5R protects the revenue by facilitating the registration of premises subject to special tax and the timely payment of that tax by the businesses subject to it. The information collected on the form is essential to TTB's collecting, processing, and accounting for these special taxes.

Form: TTB Form 5630.5R.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 7,800.

Title: Records to Support Tax Free and Tax Overpayment Sales of Firearms and Ammunition.

OMB Control Number: 1513–0128.

Type of Review: Extension without change of a currently approved collection.

Abstract: The Internal Revenue Code (IRC) at 26 U.S.C. 4181 imposes a tax on the sale of firearms and ammunition. However, under the IRC at 26 U.S.C. 4221(a), certain sales may be made tax-free, including sales made for further manufacture, export, or use as supplies on vessels or aircraft, and sales made to a State or local government or to a nonprofit education organization for their exclusive use. In addition, for such sales where the tax has been paid, the tax is considered an overpayment subject to credit or refund under the IRC at 26 U.S.C. 6416(b)(2) and (3). In order to protect the revenue, the TTB regulations in 27 CFR part 53 prescribe that those otherwise subject to this tax must maintain records, including statements or certificates containing specified information, documenting the tax-free or tax-overpaid nature of such sales. Respondents may use commercial records or self-generated supporting statement or certificates, or, for certain transactions, respondents may use TTB-provided forms, which, when completed, document the required supporting information. The required supporting information is maintained by respondents at their business premises, and, to protect the revenue, TTB may examine these records during audits.

Form: TTB Forms 5600.33, 5600.34, 5600.35, 5600.36, 5600.37.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 52,500.

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

OMB Control Number: 1513–0132.

Type of Review: Extension without change of a currently approved collection.

Abstract: TTB uses the surveys, focus groups, and other information collection instruments approved under this generic clearance to gather customer and stakeholder feedback on TTB programs in an efficient, timely manner. TTB uses the collected information to help improve service delivery and to help ensure that its customers and stakeholders have effective, efficient, and satisfactory experiences with the bureau's programs.

Form: None.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 25,000.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: July 25, 2017.

Spencer W. Clark,

Treasury PRA Clearance Officer.

[FR Doc. 2017–15975 Filed 7–27–17; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF THE TREASURY

Open Meeting of the Federal Advisory Committee on Insurance

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice of open meeting.

SUMMARY: This notice announces that the Department of the Treasury's Federal Advisory Committee on Insurance (“Committee”) will convene a meeting on Thursday, August 17, 2017, in the Cash Room, 1500 Pennsylvania Avenue NW., Washington, DC 20220, from 1:00–5:00 p.m. Eastern Time. The meeting is open to the public, and the site is accessible to individuals with disabilities.

DATES: The meeting will be held on Thursday, August 17, 2017, from 1:00–5:00p.m. Eastern Time.

ADDRESSES: The Committee meeting will be held in the Cash Room, Department of the Treasury, 1500 Pennsylvania Avenue NW., Washington, DC 20220.

The meeting will be open to the public. Because the meeting will be held in a secured facility, members of the public who plan to attend the meeting must register online at <http://www.cvent.com/d/d5q5m1> and fill out the secure online registration form. A valid email address will be required to

complete the online registration. (**Note:** The online registration will close at 11:59 p.m. Eastern Time on Tuesday, August 15, 2017.)

Requests for reasonable accommodations under Section 504 of the Rehabilitation Act should be directed to Mariam G. Harvey, Office of Civil Rights and Diversity, Department of the Treasury, at 202-622-0316 or mariam.harvey@do.treas.gov.

FOR FURTHER INFORMATION CONTACT: Daniel McCarty, Federal Insurance Office, Room 1410, Department of the Treasury, 1500 Pennsylvania Avenue NW., Washington, DC 20220 at 202-622-5892 (this is not a toll-free number). Persons who have difficulty hearing or speaking may access this number via TTY by calling the toll-free Federal Relay Service at (800) 877-8339.

SUPPLEMENTARY INFORMATION: Notice of this meeting is provided in accordance with the Federal Advisory Committee Act, 5 U.S.C. App. II, 10(a)(2), through implementing regulations at 41 CFR 102-3.150.

Public Comment: Members of the public wishing to comment on the business of the Federal Advisory Committee on Insurance are invited to submit written statements by any of the following methods:

Electronic Statements

- Send electronic comments to faci@treasury.gov.

Paper Statements

- Send paper statements triplicate to the Federal Advisory Committee on Insurance, Room 1410, Department of the Treasury, 1500 Pennsylvania Avenue NW., Washington, DC 20220. In general, the Department of the Treasury will post all statements on its Web site (<http://www.treasury.gov/about/organizational-structure/offices/Pages/Federal-Insurance.aspx>) without change, including any business or personal information provided such as names, addresses, email addresses, or telephone numbers. The Department of the Treasury will also make such statements available for public inspection and copying in the Department of the Treasury's Library, 1500 Pennsylvania Avenue NW., Washington, DC 20220, on official business days between the hours of 10:00 a.m. and 5:00 p.m. Eastern Time. You can make an appointment to inspect statements by telephoning (202)

622-0990. All statements, including attachments and other supporting materials, received are part of the public record and subject to public disclosure. You should submit only information that you wish to make available publicly.

Tentative Agenda/Topics for Discussion: This is a periodic meeting of the Federal Advisory Committee on Insurance. In this meeting, the Committee will discuss topics including: The effect of big data on the insurance industry, cyber coverage, and an insurance marketplace update.

Steven E. Seitz,

Deputy Director, Federal Insurance Office.

[FR Doc. 2017-15970 Filed 7-27-17; 8:45 am]

BILLING CODE 4810-25-P

U.S.-CHINA ECONOMIC AND SECURITY REVIEW COMMISSION

Notice of Open Public Meeting

AGENCY: U.S.-China Economic and Security Review Commission.

ACTION: Notice of open public meeting.

SUMMARY: Notice is hereby given of a meeting of the U.S.-China Economic and Security Review Commission to review and edit drafts of the 2017 Annual Report to Congress. The Commission is mandated by Congress to investigate, assess, and report to Congress annually on the "the national security implications of the economic relationship between the United States and the People's Republic of China." Pursuant to this mandate, the Commission will hold a public meeting to review and edit drafts of the 2017 Annual Report to Congress.

DATES: The meeting is scheduled for Thursday, August 10, 2017, from 9:00 a.m. to 5:00 p.m. and Friday, August 11, 2017, from 9:00 a.m. to 5:00 p.m.

ADDRESSES: 444 North Capitol Street NW., Room 233, Washington, DC 20001. Public seating is limited and will be available on a "first-come, first-served" basis. *Reservations are not required to attend the meeting.*

FOR FURTHER INFORMATION CONTACT: Any member of the public seeking further information concerning the meeting should contact Alexis Brigmon, 444 North Capitol Street NW., Suite 602, Washington, DC 20001; telephone: 202-624-1454, or via email at [\[uscc.gov\]\(mailto:uscc.gov\). *Reservations are not required to attend the meeting.*](mailto:abrigmon@</p>
</div>
<div data-bbox=)

SUPPLEMENTARY INFORMATION:

Purpose of Meeting: Pursuant to the Commission's mandate, members of the Commission will meet to review and edit drafts of the 2017 Annual Report to Congress.

The Commission is subject to the Federal Advisory Committee Act (FACA) with the enactment of the Science, State, Justice, Commerce and Related Agencies Appropriations Act, 2006 that was signed into law on November 22, 2005 (Pub. L. 109-108). In accordance with FACA, the Commission's meeting to make decisions concerning the substance and recommendations of its 2017 Annual Report to Congress are open to the public.

Topics To Be Discussed: The Commission will consider draft report sections addressing the following topics:

- U.S.-China Economic and Trade Relations, including: Year in Review: Economics Trade; and U.S. Access to China's Consumer Market.
- U.S.-China Security Relations, including: Year in Review: Security and Foreign Affairs.
- China and the World, including: China and Continental Southeast Asia; China and Northeast Asia; China and Taiwan; and China's Domestic Information Controls, Global Media Influence, and Cyber Diplomacy.

Required Accessibility Statement: The meeting will be open to the public. The Commission may recess the meeting to address administrative issues in closed session.

The Commission will also recess the meeting around noon for a lunch break. At the beginning of the lunch break, the Chairman will announce what time the meeting will reconvene.

Authority: Congress created the U.S.-China Economic and Security Review Commission in 2000 in the National Defense Authorization Act (Pub. L. 106-398), as amended by Division P of the Consolidated Appropriations Resolution, 2003 (Pub. L. 108-7), as amended by Public Law 109-108 (November 22, 2005), as amended by Public Law 113-291 (December 19, 2014).

Dated: July 24, 2017.

Michael Danis,

Executive Director, U.S.-China Economic and Security Review Commission.

[FR Doc. 2017-15948 Filed 7-27-17; 8:45 am]

BILLING CODE 1137-00-P



FEDERAL REGISTER

Vol. 82

Friday,

No. 144

July 28, 2017

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 409 and 484

Medicare and Medicaid Programs; CY 2018 Home Health Prospective Payment System Rate Update and Proposed CY 2019 Case-Mix Adjustment Methodology Refinements; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409 and 484

[CMS–1672–P]

RIN 0938–AT01

Medicare and Medicaid Programs; CY 2018 Home Health Prospective Payment System Rate Update and Proposed CY 2019 Case-Mix Adjustment Methodology Refinements; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule updates the home health prospective payment system (HH PPS) payment rates, including the national, standardized 60-day episode payment rates, the national per-visit rates, and the non-routine medical supply (NRS) conversion factor, effective for home health episodes of care ending on or after January 1, 2018. This rule also: updates the HH PPS case-mix weights using the most current, complete data available at the time of rulemaking; implements the 3rd-year of a 3-year phase-in of a reduction to the national, standardized 60-day episode payment to account for estimated case-mix growth unrelated to increases in patient acuity (that is, nominal case-mix growth) between CY 2012 and CY 2014; and discusses our efforts to monitor the potential impacts of the rebasing adjustments that were implemented in CY 2014 through CY 2017. This rule proposes case-mix methodology refinements, as well as a change in the unit of payment from 60-day episodes of care to 30-day periods of care, to be implemented for home health services beginning on or after January 1, 2019; and finally, this rule proposes changes to the Home Health Value-Based Purchasing (HHVBP) Model and to the Home Health Quality Reporting Program (HH QRP).

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 25, 2017.

ADDRESSES: In commenting, please refer to file code CMS–1672–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions under the “More Search Options” tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1672–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1672–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: For general information about the HH PPS, please send your inquiry via email to: HomehealthPolicy@cms.hhs.gov.

For information about the HHVBP model, please send your inquiry via email to: HHVBPquestions@cms.hhs.gov.

Joan Proctor, (410) 786–0949 for information about the home health quality reporting program.

SUPPLEMENTARY INFORMATION: Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. EST. To schedule an appointment to view public comments, phone 1–800–743–3951.

Table of Contents

- I. Executive Summary
 - A. Purpose
 - B. Summary of the Major Provisions
 - C. Summary of Costs and Benefits
- II. Background
 - A. Statutory Background
 - B. Current System for Payment of Home Health Services
 - C. Updates to the Home Health Prospective Payment System
 - D. Report to Congress: Home Health Study on Access to Care for Vulnerable Patient Populations and Subsequent Research and Analyses
- III. Provisions of the Proposed Rule: Payment Under the Home Health Prospective Payment System (HH PPS)
 - A. Monitoring for Potential Impacts—Affordable Care Act Rebasing Adjustments
 - B. Proposed CY 2018 HH PPS Case-Mix Weights
 - C. Proposed CY 2018 Home Health Payment Rate Update
 - D. Payments for High-Cost Outliers under the HH PPS
 - E. Proposed Implementation of the Home Health Groupings Model (HHGM) for CY 2019
- IV. Proposed Provisions of the Home Health Value-Based Purchasing (HHVBP) Model
 - A. Background
 - B. Quality Measures
 - C. Quality Measures for Future Consideration

- V. Proposed Updates to the Home Health Care Quality Reporting Program (HH QRP)
 - A. Background and Statutory Authority
 - B. General Considerations Used for the Selection of Quality Measures for the HH QRP
 - C. Accounting for Social Risk Factors in the HH QRP
 - D. Proposed Data Elements for Removal From OASIS
 - E. Proposed Collection of Standardized Patient Assessment Data Under the HH QRP
 - F. HH QRP Quality Measures Proposed Beginning With the CY 2020 HH QRP
 - G. HH QRP Quality Measures and Measure Concepts Under Consideration for Future Years
 - H. Proposed Standardized Patient Assessment Data
 - I. Proposals Relating to the Form, Manner, and Timing of Data Submission Under the HH QRP
 - J. Other Proposals for the CY 2019 HH QRP and Subsequent Years
 - K. Proposals and Policies Regarding Public Display of Quality Measure Data for the HH QRP
 - L. Proposed Mechanism for Providing Confidential Feedback Reports to HHAs
 - M. Home Health Care CAHPS® Survey (HHCAHPS)
- VI. Request for Information on CMS Flexibilities and Efficiencies
- VII. Collection of Information Requirements
 - A. Statutory Requirement for Solicitation of Comments
 - B. Collection of Information Requirements for the HH QRP
 - C. Submission of PRA-Related Comments
- VIII. Response to Public Comments
- IX. Regulatory Impact Analysis
 - A. Statement of Need
 - B. Overall Impact
 - C. Detailed Economic Analysis
 - D. Alternatives Considered
 - E. Accounting Statement and Table
 - F. Reducing Regulation and Controlling Regulatory Costs
 - G. Conclusion
- X. Federalism Analysis
- Regulation Text

Acronyms

In addition, because of the many terms to which we refer by abbreviation in this proposed rule, we are listing these abbreviations and their corresponding terms in alphabetical order below:

ACH LOS Acute Care Hospital Length of Stay
 ADL Activities of Daily Living
 AM-PAC Activity Measure for Post-Acute Care
 APU Annual Payment Update
 ASPE Assistant Secretary for Planning and Evaluation
 BBA Balanced Budget Act of 1997, Public Law 105–33
 BBRA Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, (Pub. L. 106–113)
 BIMS Brief Interview for Mental Status

BLS Bureau of Labor Statistics
 CAD Coronary Artery Disease
 CAH Critical Access Hospital
 CAM Confusion Assessment Method
 CARE Continuity Assessment Record and Evaluation
 CASPER Certification and Survey Provider Enhanced Reports
 CBSA Core-Based Statistical Area
 CCN CMS Certification Number
 CHF Congestive Heart Failure
 CMI Case-Mix Index
 CMP Civil Money Penalty
 CMS Centers for Medicare & Medicaid Services
 CoPs Conditions of Participation
 COPD Chronic Obstructive Pulmonary Disease
 CVD Cardiovascular Disease
 CY Calendar Year
 DM Diabetes Mellitus
 DRA Deficit Reduction Act of 2005, Public Law 109–171, enacted February 8, 2006
 DTI Deep Tissue Injury
 EOC End of Care
 FDL Fixed Dollar Loss
 FI Fiscal Intermediaries
 FR Federal Register
 FY Fiscal Year
 HAVEN Home Assessment Validation and Entry System
 HCC Hierarchical Condition Categories
 HCIS Health Care Information System
 HH Home Health
 HHA Home Health Agency
 HHCAHPS Home Health Care Consumer Assessment of Healthcare Providers and Systems Survey
 HH PPS Home Health Prospective Payment System
 HHGM Home Health Groupings Model
 HHQRP Home Health Quality Reporting Program
 HHRG Home Health Resource Group
 HHVBP Home Health Value-Based Purchasing
 HIPPS Health Insurance Prospective Payment System
 HVBP Hospital Value-Based Purchasing
 IADL Instrumental Activities of Daily Living
 ICD–9–CM International Classification of Diseases, Ninth Revision, Clinical Modification
 ICD–10–CM International Classification of Diseases, Tenth Revision, Clinical Modification
 IH Inpatient Hospitalization
 IMPACT Act Improving Medicare Care Transformation Act of 2014 (Pub. L. 113–185)
 IPR Interim Performance Report
 IRF Inpatient Rehabilitation Facility
 IRF-PAI IRF Patient Assessment Instrument
 IV Intravenous
 LCDS LTCH CARE Data Set
 LEF Linear Exchange Function
 LTCH Long-Term Care Hospital
 LUPA Low-Utilization Payment Adjustment
 MACRA Medicare Access and CHIP Reauthorization Act of 2015
 MAP Measure Applications Partnership
 MDS Minimum Data Set
 MEPS Medical Expenditures Panel Survey
 MFP Multifactor productivity
 MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108–173, enacted December 8, 2003
 MSA Metropolitan Statistical Area
 MSS Medical Social Services
 NQF National Quality Forum
 NQS National Quality Strategy
 NRS Non-Routine Supplies
 OASIS Outcome and Assessment Information Set
 OBRA Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–2–3, enacted December 22, 1987
 OCESAA Omnibus Consolidated and Emergency Supplemental Appropriations Act, Pub. L. 105–277, enacted October 21, 1998
 OES Occupational Employment Statistics
 OIG Office of Inspector General
 OLS Ordinary Least Squares
 OT Occupational Therapy
 OMB Office of Management and Budget
 PAC Post-Acute Care
 PAC-PRD Post-Acute Care Payment Reform Demonstration
 PAMA Protecting Access to Medicare Act of 2014
 PEP Partial Episode Payment Adjustment
 PHQ–2 Patient Health Questionnaire-2
 PPOC Primary Point of Contact
 PPS Prospective Payment System
 PRA Paperwork Reduction Act
 PRRB Provider Reimbursement Review Board
 PT Physical Therapy
 PY Performance Year
 QAP Quality Assurance Plan
 QIES Quality Improvement Evaluation System
 QRP Quality Reporting Program
 RAP Request for Anticipated Payment
 RF Renal Failure
 RFA Regulatory Flexibility Act, Pub. L. 96–354
 RHHIs Regional Home Health Intermediaries
 RIA Regulatory Impact Analysis
 ROC Resumption of Care
 SAF Standard Analytic File
 SLP Speech-Language Pathology
 SN Skilled Nursing
 SNF Skilled Nursing Facility
 SOC Start of Care
 SSI Surgical Site Infection
 TEP Technical Expert Panel
 TPS Total Performance Score
 UMRA Unfunded Mandates Reform Act of 1995.
 VAD Vascular Access Device
 VBP Value-Based Purchasing

I. Executive Summary

A. Purpose

This proposed rule would update the payment rates for home health agencies (HHAs) for calendar year (CY) 2018, as required under section 1895(b) of the Social Security Act (the Act). This proposed rule would update the case-mix weights under section 1895(b)(4)(A)(i) and (b)(4)(B) of the Act for CY 2018 and implement a 0.97 percent reduction to the national, standardized 60-day episode payment amount to account for case-mix growth

unrelated to increases in patient acuity (that is, nominal case-mix growth) between CY 2012 and CY 2014, under the authority of section 1895(b)(3)(B)(iv) of the Act. For home health services beginning on or after January 1, 2019, this rule also proposes case-mix methodology refinements under the authority set out at sections 1895(b)(4)(A)(i) and (b)(4)(B) of the Act, and a change in the unit of payment from a 60-day episode of care to a 30-day period of care under the authority set out at section 1895(b)(2) of the Act. Additionally, this rule proposes changes to: The Home Health Value Based Purchasing (HHVBP) model under the authority of section 1115A of the Act; and the Home Health Quality Reporting Program (HH QRP) requirements under the authority of section 1895(b)(3)(B)(v) of the Act.

B. Summary of the Major Provisions

Section III.A of this rule discusses our efforts to monitor for potential impacts due to the rebasing adjustments implemented in CY 2014 through CY 2017, as mandated by section 3131(a) of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148, enacted March 23, 2010) as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, enacted March 30, 2010), collectively referred to as the “Affordable Care Act”. In the CY 2015 HH PPS final rule (79 FR 66072), we finalized our proposal to recalibrate the case-mix weights every year with the most current and complete data available at the time of rulemaking. In section III.B of this rule, we are recalibrating the HH PPS case-mix weights, using the most current cost and utilization data available, in a budget neutral manner. Also in section III.B of this rule, as finalized in the CY 2016 HH

PPS final rule (80 FR 68624), we are implementing a reduction to the national, standardized 60-day episode payment rate for CY 2018 of 0.97 percent to account for estimated case-mix growth unrelated to increases in patient acuity (that is, nominal case-mix growth) between CY 2012 and CY 2014.

In section III.C of this proposed rule, we would update the payment rates under the HH PPS by 1 percent for CY 2018 in accordance with section 411(d) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted April 16, 2015) which amended section 1895(b)(3)(B) of the Act. Additionally, section III.C of this rule, would update the CY 2018 home health wage index using FY 2014 hospital cost report data. In section III.D of this proposed rule, we note that the fixed-dollar loss ratio would remain 0.55 for CY 2018 to pay up to, but no more than, 2.5 percent of total payments as outlier payments, as required by section 1895(b)(5)(A) of the Act.

In section III.E of this rule we are proposing to implement case-mix methodology refinements and a change in the unit of payment from a 60-day episode of care to a 30-day period of care, effective for home health services beginning on or after January 1, 2019. The proposed home health groupings model (HHGM) relies more heavily on clinical characteristics and other patient information to place patients into meaningful payment categories, while eliminating therapy service use thresholds that are currently used to case-mix adjust payments under the HH PPS. This includes proposed changes in the episode timing categories, the addition of an admission source category, the creation of six clinical groups used to categorize patients based on their primary reason for home health care, revised functional levels and

corresponding OASIS items, the addition of a comorbidity adjustment, and a proposed change in the Low-Utilization Payment Adjustment (LUPA) threshold. The LUPA add-on policy, the partial [episode] payment adjustment policy, and the methodology used to calculate payments for high-cost outliers would remain unchanged except for occurring on a 30-day basis rather than a 60-day basis.

In section IV of this rule, we are proposing changes to the Home Health Value-Based Purchasing (HHVBP) Model implemented January 1, 2016. We are proposing to amend the definition of “applicable measure” to specify that the HHA would have to submit a minimum of 40 completed surveys for Home Health Care Consumer Assessment of Healthcare Providers and Systems (HCAHPS) measures, for purposes of receiving a performance score for any of the HCAHPS measures, and for performance year (PY) 3 and subsequent years, to remove the Outcome and Assessment Information Set (OASIS)-based measure, Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care, from the set of applicable measures. We are also soliciting public comments on composite quality measures for future consideration.

In section V of this rule, we propose updates to the Home Health Quality Reporting Program, including: The replacement of one quality measure, the adoption of two new quality measures, the reporting of standardized patient assessment data in five categories described under the IMPACT Act, data submission requirements, exception and extension requirements, and reconsideration and appeals procedures.

C. Summary of Costs and Benefits

TABLE 1—SUMMARY OF COSTS AND TRANSFERS

Provision description	Costs	Transfers
CY 2018 HH PPS Payment Rate Update.		The overall economic impact of the HH PPS payment rate update is an estimated –\$80 million (–0.4 percent) in payments to HHAs.
CY 2018 HHVBP Model		The overall economic impact of the HHVBP Model provision for CY 2018 through 2022 is an estimated \$378 million in total savings from a reduction in unnecessary hospitalizations and SNF usage as a result of greater quality improvements in the HH industry (none of which is attributable to the changes proposed in this proposed rule). As for payments to HHAs, there are no aggregate increases or decreases expected to be applied to the HHAs competing in the model.
CY 2019 HH QRP	The overall economic impact of the HH QRP changes is a savings to HHAs of an estimated \$44.9 million, beginning January 1, 2019.	

TABLE 1—SUMMARY OF COSTS AND TRANSFERS—Continued

Provision description	Costs	Transfers
CY 2019 HH PPS Case-Mix Adjustment Methodology Refinements.		The overall impact of the proposed HH PPS case-mix adjustment methodology refinements, including a change in the unit of payment from 60-day episodes to 30-day periods of care, is an estimated –\$950 million (–4.3 percent) in payments to HHAs in CY 2019 if the refinements are implemented in a non-budget neutral manner for 30-day periods of care beginning on or after January 1, 2019. The overall impact is an estimated –\$480 million (–2.2 percent) in payments to HHAs in CY 2019 if the refinements are implemented in a partially budget-neutral manner.

II. Background

A. Statutory Background

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33, enacted August 5, 1997), significantly changed the way Medicare pays for Medicare HH services. Section 4603 of the BBA mandated the development of the HH PPS. Until the implementation of the HH PPS on October 1, 2000, HHAs received payment under a retrospective reimbursement system.

Section 4603(a) of the BBA mandated the development of a HH PPS for all Medicare-covered HH services provided under a plan of care (POC) that were paid on a reasonable cost basis by adding section 1895 of the Act, entitled “Prospective Payment For Home Health Services.” Section 1895(b)(1) of the Act requires the Secretary to establish a HH PPS for all costs of HH services paid under Medicare.

Section 1895(b)(3)(A) of the Act requires the following: (1) The computation of a standard prospective payment amount include all costs for HH services covered and paid for on a reasonable cost basis and that such amounts be initially based on the most recent audited cost report data available to the Secretary; and (2) the standardized prospective payment amount be adjusted to account for the effects of case-mix and wage levels among HHAs.

Section 1895(b)(3)(B) of the Act addresses the annual update to the standard prospective payment amounts by the HH applicable percentage increase. Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act require the standard prospective payment amount to be adjusted for case-mix and geographic differences in wage levels. Section 1895(b)(4)(B) of the Act requires the establishment of an appropriate case-mix change adjustment factor for significant variation in costs among different units of services.

Similarly, section 1895(b)(4)(C) of the Act requires the establishment of wage adjustment factors that reflect the relative level of wages, and wage-related costs applicable to HH services furnished in a geographic area compared to the applicable national average level. Under section 1895(b)(4)(C) of the Act, the wage-adjustment factors used by the Secretary may be the factors used under section 1886(d)(3)(E) of the Act.

Section 1895(b)(5) of the Act gives the Secretary the option to make additions or adjustments to the payment amount otherwise paid in the case of outliers due to unusual variations in the type or amount of medically necessary care. Section 3131(b)(2) of the Affordable Care Act revised section 1895(b)(5) of the Act so that total outlier payments in a given year would not exceed 2.5 percent of total payments projected or estimated. The provision also made permanent a 10 percent agency-level outlier payment cap.

In accordance with the statute, as amended by the BBA, we published a final rule in the July 3, 2000 **Federal Register** (65 FR 41128) to implement the HH PPS legislation. The July 2000 final rule established requirements for the new HH PPS for HH services as required by section 4603 of the BBA, as subsequently amended by section 5101 of the Omnibus Consolidated and Emergency Supplemental Appropriations Act for Fiscal Year 1999 (OCESAA), (Pub. L. 105–277, enacted October 21, 1998); and by sections 302, 305, and 306 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, (BBRA) (Pub. L. 106–113, enacted November 29, 1999). The requirements include the implementation of a HH PPS for HH services, consolidated billing requirements, and a number of other related changes. The HH PPS described in that rule replaced the retrospective reasonable cost-based system that was used by Medicare for the payment of HH services under Part A and Part B. For a complete and full description of the HH

PPS as required by the BBA, see the July 2000 HH PPS final rule (65 FR 41128 through 41214).

Section 5201(c) of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171, enacted February 8, 2006) added new section 1895(b)(3)(B)(v) to the Act, requiring HHAs to submit data for purposes of measuring health care quality, and links the quality data submission to the annual applicable percentage increase. This data submission requirement is applicable for CY 2007 and each subsequent year. If an HHA does not submit quality data, the HH market basket percentage increase is reduced by 2 percentage points. In the November 9, 2006 **Federal Register** (71 FR 65884, 65935), we published a final rule to implement the pay-for-reporting requirement of the DRA, which was codified at § 484.225(h) and (i) in accordance with the statute. The pay-for-reporting requirement was implemented on January 1, 2007.

The Affordable Care Act made additional changes to the HH PPS. One of the changes in section 3131 of the Affordable Care Act is the amendment to section 421(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted on December 8, 2003) as amended by section 5201(b) of the DRA. Section 421(a) of the MMA, as amended by section 3131 of the Affordable Care Act, requires that the Secretary increase, by 3 percent, the payment amount otherwise made under section 1895 of the Act, for HH services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act) with respect to episodes and visits ending on or after April 1, 2010, and before January 1, 2016.

Section 210 of the MACRA amended section 421(a) of the MMA to extend the rural add-on for 2 more years. Section 421(a) of the MMA, as amended by section 210 of the MACRA, requires that the Secretary increase, by 3 percent, the payment amount otherwise made under section 1895 of the Act, for HH services

provided in a rural area (as defined in section 1886(d)(2)(D) of the Act) with respect to episodes and visits ending on or after April 1, 2010, and before January 1, 2018. Section 411(d) of MACRA amended section 1895(b)(3)(B) of the Act such that for home health payments for CY 2018, the market basket percentage increase shall be 1 percent.

B. Current System for Payment of Home Health Services

Generally, Medicare currently makes payment under the HH PPS on the basis of a national, standardized 60-day episode payment rate that is adjusted for the applicable case-mix and wage index. The national, standardized 60-day episode rate includes the six HH disciplines (skilled nursing, HH aide, physical therapy, speech-language pathology, occupational therapy, and medical social services). Payment for non-routine supplies (NRS) is not part of the national, standardized 60-day episode rate, but is computed by multiplying the relative weight for a particular NRS severity level by the NRS conversion factor. Payment for durable medical equipment covered under the HH benefit is made outside the HH PPS payment system. To adjust for case-mix, the HH PPS uses a 153-category case-mix classification system to assign patients to a home health resource group (HHRG). The clinical severity level, functional severity level, and service utilization are computed from responses to selected data elements in the OASIS assessment instrument and are used to place the patient in a particular HHRG. Each HHRG has an associated case-mix weight which is used in calculating the payment for an episode. Therapy service use is measured by the number of therapy visits provided during the episode and can be categorized into nine visit level categories (or thresholds): 0–5; 6–9; 10; 11–13; 14–15; 16–17; 18–19; and 20 or more visits.

For episodes with four or fewer visits, Medicare pays national per-visit rates based on the discipline(s) providing the services. An episode consisting of four or fewer visits within a 60-day period receives what is referred to as a low-utilization payment adjustment (LUPA). Medicare also adjusts the national standardized 60-day episode payment rate for certain intervening events that are subject to a partial episode payment adjustment (PEP adjustment). For certain cases that exceed a specific cost threshold, an outlier adjustment may also be available.

C. Updates to the Home Health Prospective Payment System

As required by section 1895(b)(3)(B) of the Act, we have historically updated the HH PPS rates annually in the **Federal Register**. The August 29, 2007 final rule with comment period set forth an update to the 60-day national episode rates and the national per-visit rates under the HH PPS for CY 2008. The CY 2008 HH PPS final rule included an analysis performed on CY 2005 HH claims data, which indicated a 12.78 percent increase in the observed case-mix since 2000. Case-mix represents the variations in conditions of the patient population served by the HHAs. Subsequently, a more detailed analysis was performed on the 2005 case-mix data to evaluate if any portion of the 12.78 percent increase was associated with a change in the actual clinical condition of HH patients. We identified 8.03 percent of the total case-mix change as real, and therefore, decreased the 12.78 percent of total case-mix change by 8.03 percent to get a final nominal case-mix increase measure of 11.75 percent ($0.1278 * (1 - 0.0803) = 0.1175$).

To account for the changes in case-mix that were not related to an underlying change in patient health status, we implemented a reduction, over 4 years, to the national, standardized 60-day episode payment rates. That reduction was to be 2.75 percent per year for 3 years beginning in CY 2008 and 2.71 percent for the fourth year in CY 2011. In the CY 2011 HH PPS final rule (76 FR 68532), we updated our analyses of case-mix change and finalized a reduction of 3.79 percent, instead of 2.71 percent, for CY 2011 and deferred finalizing a payment reduction for CY 2012 until further study of the case-mix change data and methodology was completed.

In the CY 2012 HH PPS final rule (76 FR 68526), we updated the 60-day national episode rates and the national per-visit rates. In addition, as discussed in the CY 2012 HH PPS final rule (76 FR 68528), our analysis indicated that there was a 22.59 percent increase in overall case-mix from 2000 to 2009 and that only 15.76 percent of that overall observed case-mix percentage increase was due to real case-mix change. As a result of our analysis, we identified a 19.03 percent nominal increase in case-mix. At that time, to fully account for the 19.03 percent nominal case-mix growth identified from 2000 to 2009, we finalized a 3.79 percent payment reduction in CY 2012 and a 1.32 percent payment reduction for CY 2013.

In the CY 2013 HH PPS final rule (77 FR 67078), we implemented a 1.32 percent reduction to the payment rates for CY 2013 to account for nominal case-mix growth from 2000 through 2010. When taking into account the total measure of case-mix change (23.90 percent) and the 15.97 percent of total case-mix change estimated as real from 2000 to 2010, we obtained a final nominal case-mix change measure of 20.08 percent from 2000 to 2010 ($0.2390 * (1 - 0.1597) = 0.2008$). To fully account for the remainder of the 20.08 percent increase in nominal case-mix beyond that which was accounted for in previous payment reductions, we estimated that the percentage reduction to the national, standardized 60-day episode rates for nominal case-mix change would be 2.18 percent. Although we considered proposing a 2.18 percent reduction to account for the remaining increase in measured nominal case-mix, we finalized the 1.32 percent payment reduction to the national, standardized 60-day episode rates in the CY 2012 HH PPS final rule (76 FR 68532).

Section 3131(a) of the Affordable Care Act requires that, beginning in CY 2014, we apply an adjustment to the national, standardized 60-day episode rate and other amounts that reflect factors such as changes in the number of visits in an episode, the mix of services in an episode, the level of intensity of services in an episode, the average cost of providing care per episode, and other relevant factors. Additionally, we must phase in any adjustment over a 4-year period in equal increments, not to exceed 3.5 percent of the amount (or amounts) as of the date of enactment of the Affordable Care Act, and fully implement the rebasing adjustments by CY 2017. The statute specifies that the maximum rebasing adjustment is to be no more than 3.5 percent per year of the CY 2010 rates. Therefore, in the CY 2014 HH PPS final rule (78 FR 72256) for each year, CY 2014 through CY 2017, we finalized a fixed-dollar reduction to the national, standardized 60-day episode payment rate of \$80.95 per year, increases to the national per-visit payment rates per year, and a decrease to the NRS conversion factor of 2.82 percent per year. We also finalized three separate LUPA add-on factors for skilled nursing, physical therapy, and speech-language pathology and removed 170 diagnosis codes from assignment to diagnosis groups in the HH PPS Grouper. In the CY 2015 HH PPS final rule (79 FR 66032), we implemented the 2nd year of the 4 year phase-in of the rebasing adjustments to the HH PPS payment rates and made changes to the

HH PPS case-mix weights. In addition, we simplified the face-to-face encounter regulatory requirements and the therapy reassessment timeframes.

In the CY 2016 HH PPS final rule (80 FR 68624), we implemented the 3rd year of the 4-year phase-in of the rebasing adjustments to the national, standardized 60-day episode payment amount, the national per-visit rates and the NRS conversion factor (as outlined above). In the CY 2016 HH PPS final rule, we also recalibrated the HH PPS case-mix weights, using the most current cost and utilization data available, in a budget neutral manner and finalized reductions to the national, standardized 60-day episode payment rate in CY 2016, CY 2017, and CY 2018 of 0.97 percent in each year to account for estimated case-mix growth unrelated to increases in patient acuity (that is, nominal case-mix growth) between CY 2012 and CY 2014. Finally, section 421(a) of the MMA, as amended by section 210 of the MACRA, extended the payment increase of 3 percent for HH services provided in rural areas (as defined in section 1886(d)(2)(D) of the Act) to episodes or visits ending before January 1, 2018.

In the CY 2017 HH PPS final rule (81 FR 76702), we implemented the last year of the 4-year phase-in of the rebasing adjustments to the national, standardized 60-day episode payment amount, the national per-visit rates and the NRS conversion factor (as outlined above). We also finalized changes to the methodology used to calculate outlier payments under the authority of section 1895(b)(5) of the Act. Lastly, in accordance with section 1834(s) of the Act, as added by section 504(a) of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113, enacted December 18, 2015), we implemented changes in payment for furnishing Negative Pressure Wound Therapy (NPWT) using a disposable device for patients under a home health plan of care for which payment would otherwise be made under section 1895(b) of the Act.

D. Report to Congress: Home Health Study on Access to Care for Vulnerable Patient Populations and Subsequent Research and Analyses

Section 3131(d) of the Affordable Care Act required CMS to conduct a study on home health agency costs involved with providing ongoing access to care to low-income Medicare beneficiaries or beneficiaries in medically underserved areas, and in treating beneficiaries with varying levels of severity of illness and submit a report to Congress. As discussed in the CY 2016 HH PPS proposed rule (80 FR 39840) and the CY

2017 HH PPS proposed rule (81 FR 43744), the findings from the Report to Congress on the “Medicare Home Health Study: An Investigation on Access to Care and Payment for Vulnerable Patient Populations”, found that payment accuracy could be improved under the current payment system, particularly for patients with certain clinical characteristics requiring more nursing care than therapy.¹

The research for the Report to Congress, released in December 2014, consisted of extensive analysis of both survey and administrative data. The CMS-developed surveys were given to physicians who referred vulnerable patient populations to Medicare home health and to Medicare-certified HHAs.² The response rates were 72 percent and 59 percent for the HHA and physician surveys, respectively. The results of the survey revealed that over 80 percent of respondent HHAs and over 90 percent of respondent physicians reported that access to home health care for Medicare fee-for-service beneficiaries in their local area was excellent or good. When survey respondents reported access issues, specifically their inability to place or admit Medicare fee-for-service patients into home health, the most common reason reported (64 percent of respondent HHAs surveyed) was that the patients did not qualify for the Medicare home health benefit. HHAs and physicians also cited family or caregiver issues as an important contributing factor in the inability to admit or place patients. Only 17.2 percent of HHAs and 16.7 percent of physicians reported insufficient payment as an important contributing factor in the inability to admit or place patients. The results of the CMS-conducted surveys suggested that CMS’ ability to improve access for certain vulnerable patient populations through payment policy may be limited. However, we are able to revise the case-mix system to minimize differences in payment that could potentially be serving as a barrier to receiving care. In this rule, we propose to better align payment with resource use so that it reduces HHAs’ financial incentives to select certain patients over others.

However, we also performed an analysis of Medicare administrative data (CY 2010 Medicare claims and cost

report data) and calculated margins for episodes of care. This was done because margin differences associated with patient clinical and social characteristics can indicate whether financial incentives exist in the current HH PPS to provide home health care for certain types of patients over others. Lower margins, if systematically associated with care for vulnerable patient populations, may indicate financial disincentives for HHAs to admit these patients, potentially creating access to care issues. The findings from the data analysis found that certain patient characteristics appear to be strongly associated with margin levels, and thus may create financial incentives to select certain patients over others. Margins were estimated to be lower for patients who required parenteral nutrition, who had traumatic wounds or ulcers, or required substantial assistance in bathing. For example, in CY 2010, episodes for patients with parenteral nutrition were, on average, associated with a \$178.53 lower margin than episodes for patients without parenteral nutrition. Given that these variables are already included in the HH PPS case-mix system, the results indicated that modifications to the way the current case-mix system accounts for resource use differences may be needed to mitigate any financial incentives to select certain patients over others. Margins were also lower for beneficiaries who were admitted after acute or post-acute stays or who had certain poorly-controlled clinical conditions, such as poorly-controlled pulmonary disorders, indicating that accounting for additional patient characteristic variables in the HH PPS case-mix system may also reduce financial incentives to select certain types of patients over others. More information on the results from the Home Health Study required by section 3131(d) of the Affordable Care Act can be found in the Report to Congress on the “Medicare Home Health Study: An Investigation on Access to Care and Payment for Vulnerable Patient Populations” available at <https://www.cms.gov/center/provider-Type/home-Health-Agency-HHA-Center.html>.

Section 3131(d)(5) of the Affordable Care Act allowed for the Secretary to determine whether a Medicare demonstration project is appropriate to conduct based on the result of the Home Health Study. If the Secretary determined it was appropriate to conduct the demonstration project under this subsection, the Secretary was to conduct the project for a four year period beginning not later than January

¹ The Report to Congress can be found in its entirety at <https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/HomeHealthPPS/Downloads/HH-Report-to-Congress.pdf>.

² For the purposes of the surveys, “vulnerable patient populations” were defined as beneficiaries who were either eligible for the Part D low-income subsidy (LIS) 27 or residing in a health professional shortage area (HPSA).

1, 2015. We did not determine that it was appropriate to conduct a demonstration project based on the findings from the Home Health Study. Rather, the findings from the Home Health Study suggested that follow-on work should be conducted to better align payments with costs under the authority of section 1895 of the Act.

In addition to the findings from the Report to Congress on the “Medicare Home Health Study: An Investigation on Access to Care and Payment for Vulnerable Patient Populations”, concerns have also been raised about the use of therapy thresholds in the current payment system. Under the current payment system, HHAs receive higher payments for providing more therapy visits once certain thresholds are reached. As a result, the average

number of therapy visits per 60-day episode of care have increased since the implementation of the HH PPS, while the number of skilled nursing and home health aide visits have decreased over the same time period as shown in Figure 3 in section III.A of this rule. A study examining an option of using predicted, rather than actual, therapy visits in the HH found that in 2013, 58 percent of home health episodes included some therapy services, and these episodes accounted for 72 percent of all Medicare home health payments.³ Figure 1 from that study demonstrates that the percentage of episodes, and the average episode payment by the number of therapy visits for episodes with at least one therapy visit in 2013 increased sharply in therapy provision just over payment thresholds at 6, 7, and 16.

According to the study, the presence of sharp increases in the percentage of episodes just above payment thresholds suggests a response to financial incentives in the home health payment system. Similarly, between 2008 and 2013, MedPAC reported a 26 percent increase in the number of episodes with at least 6 therapy visits, compared with a 1 percent increase in the number of episodes with five or fewer therapy visits.⁴ CMS analysis demonstrates that the average share of therapy visits across all 60-day episodes of care increased from 9 percent of all visits in 1997, prior to the implementation of the HH PPS (see 64 FR 58151), to 39 percent of all visits in 2015 (see Table 2 in section III.A. of this proposed rule).

FIGURE 1: Percent of Episodes and Average Payment by Number of Therapy Visits

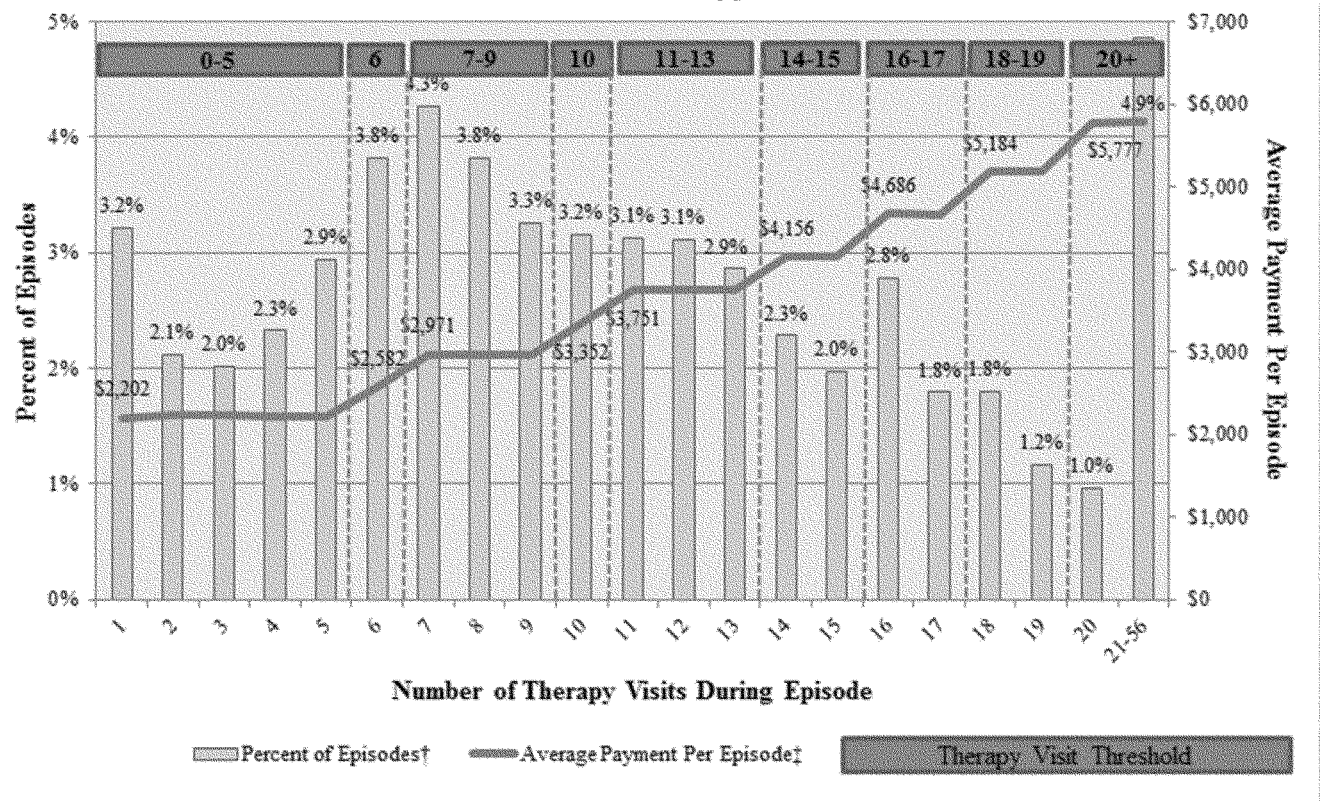


Figure 1 suggests that HHAs may be responding to financial incentives in the home health payment system when making care plan decisions. Additionally, an investigation into the

therapy practices of the four largest publically-traded home health companies, conducted by the Senate Committee on Finance in 2010, found that three out of the four companies

investigated “encouraged therapists to target the most profitable number of therapy visits, even when patient need alone may not have justified such patterns”.⁵ The Committee on Finance

³ Fout B, Plotzke M, Christian T. (2016). Using Predicted Therapy Visits in the Medicare Home Health Prospective Payment System. *Home Health Care Management & Practice*, 29(2), 81–90. <http://journals.sagepub.com/doi/abs/10.1177/1084822316678384>.

⁴ Medicare Payment Advisory Commission (MedPAC). “Home Health Care Services.” *Report to Congress: Medicare Payment Policy*. Washington, DC, March 2015. P. 223. Accessed on March 28, 2017 at: <http://www.medpac.gov/docs/default->

[source/reports/mar2015_entirereport_revised.pdf?sfvrsn=0](source/reports/mar2015_entirereport_revised.pdf?sfvrsn=0).
⁵ Committee on Finance, United States Senate. *Staff Report on Home Health and the Medicare*

investigation also highlighted the abrupt and dramatic responses the home health industry has taken to maximize reimbursement under the therapy threshold models (both the original 10-visit threshold model and under the revised thresholds implemented in the CY 2008 HH PPS final rule (72 FR 49762)). Under the HH PPS, the report noted that HHAs have broad discretion over the number of therapy visits to provide patients and therefore have control of the single-largest variable in determining reimbursement and overall margins. The report recommended that CMS closely examine a future payment approach that focuses on patient well-being and health characteristics, rather than the numerical utilization measures.

MedPAC also continues to recommend the removal of the therapy thresholds used for determining payment from the HH PPS, as it believes that such thresholds run counter to the goals of a prospective payment system, create financial incentives that detract from a focus on patient characteristics and care needs when agencies are setting plans of care for their patients, and incentivize unnecessary therapy utilization. For the average HHA, according to MedPAC, the increase in payment for therapy visits rises faster than costs resulting in financial incentives for HHAs to overprovide therapy services.⁶ HHAs that provide more therapy episodes tend to be more profitable and this higher profitability and rapid growth in the number of therapy episodes suggest that financial incentives are causing agencies to favor therapy services when possible.⁷ Eliminating therapy as a payment factor would base home health payment solely on patient characteristics, which is a more patient-focused approach to payment, as recommended by both MedPAC and previously by the Senate Committee on Finance.

After considering the findings from the Report to Congress and

recommendations from MedPAC and the Senate Committee on Finance, CMS, along with our contractor, conducted additional research on ways to improve the payment accuracy under the current payment system. Exploring all options and different models ultimately led us to further develop the Home Health Groupings Model (HHGM) proposal. The HHGM proposal uses 30-day periods, rather than 60-day episodes, and relies more heavily on clinical characteristics and other patient information (for example, principal diagnosis, functional level, comorbid conditions, admission source, and timing) to place patients into meaningful payment categories, rather than the current therapy driven system. We believe this patient-centered approach is consistent with how clinicians differentiate between home health patients and would improve payment accuracy and access for medically complex cases and not just cases receiving therapy. The HHGM proposal leverages many of the same aspects of the current system; however, the major differences between the current system and the HHGM proposal include a change from a 60-day to a 30-day billing cycle and the elimination of the therapy thresholds in the case-mix system.

We shared the analyses and development of the HHGM with both internal and external stakeholders via technical expert panels, clinical workgroups, special open door forums, and in the CY 2016 HH PPS proposed rule (80 FR 39840) and the CY 2017 HH PPS proposed rule (81 FR 43744). Most recently, we posted a detailed technical report on the CMS Web site in December of 2016.⁸ After posting the technical report for the public to review, we also held additional technical expert panel and clinical workgroup webinars to garner feedback from the industry and conducted a National Provider call that occurred in January 2017 to solicit

feedback from external stakeholders.⁹ The feedback we received during the National Provider call on the HHGM was positive. We discuss the HHGM proposal further below, in section III.E, and seek public comment on this proposal and the underlying analyses.

III. Provisions of the Proposed Rule: Payment Under the Home Health Prospective Payment System (HH PPS)

A. Monitoring for Potential Impacts—Affordable Care Act Rebasing Adjustments

1. Analysis of FY 2015 HHA Cost Report Data

As part of our efforts in monitoring the potential impacts of the rebasing adjustments finalized in the CY 2014 HH PPS final rule (78 FR 72293), we continue to update our analysis of home health cost report and claims data. Previous years' cost report and claims data analyses and results can be found in the CY 2017 HH PPS proposed rule (81 FR 43719 through 43720). For this proposed rule, we analyzed 2015 HHA cost report data and 2015 HHA claims data. To determine the 2015 average cost per visit per discipline, we applied the same trimming methodology outlined in the CY 2014 HH PPS proposed rule (78 FR 40284) and weighted the costs per visit from the 2015 cost reports by size, facility type, and urban/rural location so the costs per visit were nationally representative according to 2015 claims data. The 2015 average number of visits was taken from 2015 claims data. We estimated the cost of a 60-day episode in CY 2015 to be \$2,449.01 using 2015 cost report data as shown in Table 2. However, the national, standardized 60-day episode payment amount in CY 2015 was \$2,961.38. For CY 2015, on average, payments were 21 percent higher than costs ((\$2,961.38—\$2,449.01)/\$2,449.01).

TABLE 2—2015 ESTIMATED COST PER EPISODE

Discipline	2015 Average costs per visit	2015 Average number of visits	2015 60-day episode costs
Skilled Nursing	\$132.48	8.93	\$1,183.05
Physical Therapy	156.32	5.39	842.56

Therapy Threshold. Washington, DC, 2011.

Accessed on March 28, 2017 at https://www.finance.senate.gov/imo/media/doc/Home_Health_Report_Final4.pdf.

⁶ Medicare Payment Advisory Commission (MedPAC). "Home Health Services." *Report to Congress: Medicare Payment Policy*. Washington, DC, March 2011. P. 182–183. Accessed on March 28, 2017 at http://www.medpac.gov/docs/default-source/reports/Mar11_Ch08.pdf?sfvrsn=0.

⁷ Medicare Payment Advisory Commission (MedPAC). "Home Health Care Services." *Report to Congress: Medicare Payment Policy*. Washington, DC, March 2017. P. 243–244. Accessed on March 28, 2017 at http://www.medpac.gov/docs/default-source/reports/mar17_medpac_ch9.pdf?sfvrsn=0.

⁸ Ab Associates. *Medicare Home Health Prospective Payment System: Case-Mix Methodology Refinements. Overview of the Home Health Groupings Model*. Cambridge, MA, November 18, 2016. Accessed on April 27, 2017 at:

<https://downloads.cms.gov/files/hhgm%20technical%20report%20120516%20sxf.pdf>.

⁹ Centers for Medicare & Medicaid Services (CMS). "Home Health Groupings Model Technical Report Call." Baltimore, MD, January 18, 2017. Accessed on April 27, 2017 at: <https://www.cms.gov/Outreach-and-Education/Outreach/NPC/National-Provider-Calls-and-Events-Items/2017-01-18-Home-Health.html?DLPage=2&DLEntries=10&DLSort=0&DLSortDir=descending>.

TABLE 2—2015 ESTIMATED COST PER EPISODE—Continued

Discipline	2015 Average costs per visit	2015 Average number of visits	2015 60-day episode costs
Occupational Therapy	154.64	1.41	218.04
Speech Pathology	170.96	0.29	49.58
Medical Social Services	220.07	0.14	30.81
Home Health Aides	62.80	1.99	124.97
Total		18.15	2,449.01

Source: Medicare cost reports pulled in February 2017 and Medicare claims data from 2014 and 2015 for episodes (excluding low-utilization payment adjusted episodes and partial-episode-payment adjusted episodes), linked to OASIS assessments for episodes ending in CY 2015.

2. Analysis of CY 2016 HHA Claims Data

In the CY 2014 HH PPS final rule (78 FR 72283), some commenters expressed concern that the rebasing of the HH PPS payment rates would result in HHA closures and would therefore diminish access to home health services. In addition to examining more recent cost report data, for this proposed rule we examined home health claims data from the first 3 years of the 4-year phase-in of the rebasing adjustments (CY 2014, CY 2015, and CY 2016), the first calendar year of the HH PPS (CY 2001), and claims data for 2 years before

implementation of the rebasing adjustments (CY 2012 and CY 2013). Analysis of CY 2016 home health claims data indicates that the number of episodes and the number of home health users that received at least one episode of care remained virtually the same (change of less than 1 percent) from 2015 to 2016, while the number of FFS beneficiaries increased 2 percent from 2015 to 2016. Between 2013 and 2014 there appears to be a net decrease in the number of HHAs billing Medicare for home health services of 1.6 percent, a continued decrease of 1.7 percent from 2014 to 2015, and a decrease of 2.5 percent from 2015 to 2016. The number

of home health users, as a percentage of FFS beneficiaries, appears to have slightly decreased from 9.0 percent in 2012 to 8.7 percent in 2016, but remains higher than the 6.9 percent in 2001. In CY 2016, there were 2.9 HHAs per 10,000 FFS beneficiaries, which is still markedly higher than the 1.9 HHAs per 10,000 FFS beneficiaries observed close to the implementation of the HH PPS in 2001 (see Table 3). Therefore, the rebasing adjustments made to the HH PPS payment rates in CYs 2014 through 2016 do not appear to have resulted in significant HHA closures or otherwise diminished access to home health services.

TABLE 3—HOME HEALTH STATISTICS, CY 2001 AND CY 2012 THROUGH CY 2016¹⁰

	2001	2012	2013	2014	2015	2016
Number of episodes	3,896,502	6,727,875	6,708,923	6,451,283	6,340,932	6,294,234
Beneficiaries receiving at least 1 episode (Home Health Users)	2,412,318	3,446,122	3,484,579	3,381,635	3,365,512	3,350,174
Part A and/or B FFS beneficiaries	34,899,167	38,224,640	38,505,609	38,506,534	38,506,534	38,555,150
Episodes per Part A and/or B FFS beneficiaries	0.11	0.18	0.17	0.17	0.17	0.16
Home health users as a percentage of Part A and/or B FFS beneficiaries	6.9%	9.0%	9.0%	8.8%	8.8%	8.7%
HHAs providing at least 1 episode	6,511	11,746	11,889	11,693	11,381	11,102
HHAs per 10,000 Part A and/or B FFS beneficiaries	1.9	3.1	3.1	3.0	3.0	2.9

Source: National claims history (NCH) data obtained from Chronic Condition Warehouse (CCW)—Accessed on May 14, 2014 and August 19, 2014 for CY 2011, CY 2012, and CY 2013 data; accessed on May 7, 2015 for CY 2001 and CY 2014 data; accessed on April 7, 2016 for CY 2015 data; and accessed on March 20, 2017 for CY 2016 data and Medicare enrollment information obtained from the CCW Master Beneficiary Summary File. Beneficiaries are the total number of beneficiaries in a given year with at least 1 month of Part A and/or Part B Fee-for-Service coverage without having any months of Medicare Advantage coverage.

Note(s): These results include all episode types (Normal, PEP, Outlier, LUPA) and also include episodes from outlying areas (outside of 50 States and District of Columbia). Only episodes with a through date in the year specified are included. Episodes with a claim frequency code equal to “0” (“Non-payment/zero claims”) and “2” (“Interim—first claim”) are excluded. If a beneficiary is treated by providers from multiple states within a year the beneficiary is counted within each state’s unique number of beneficiaries served.

In addition to examining home health claims data from the first three years of the implementation of rebasing adjustments required by the Affordable Care Act, we examined trends in home health utilization for all years starting in CY 2001 and up through CY 2016. Figure 2, displays the average number of

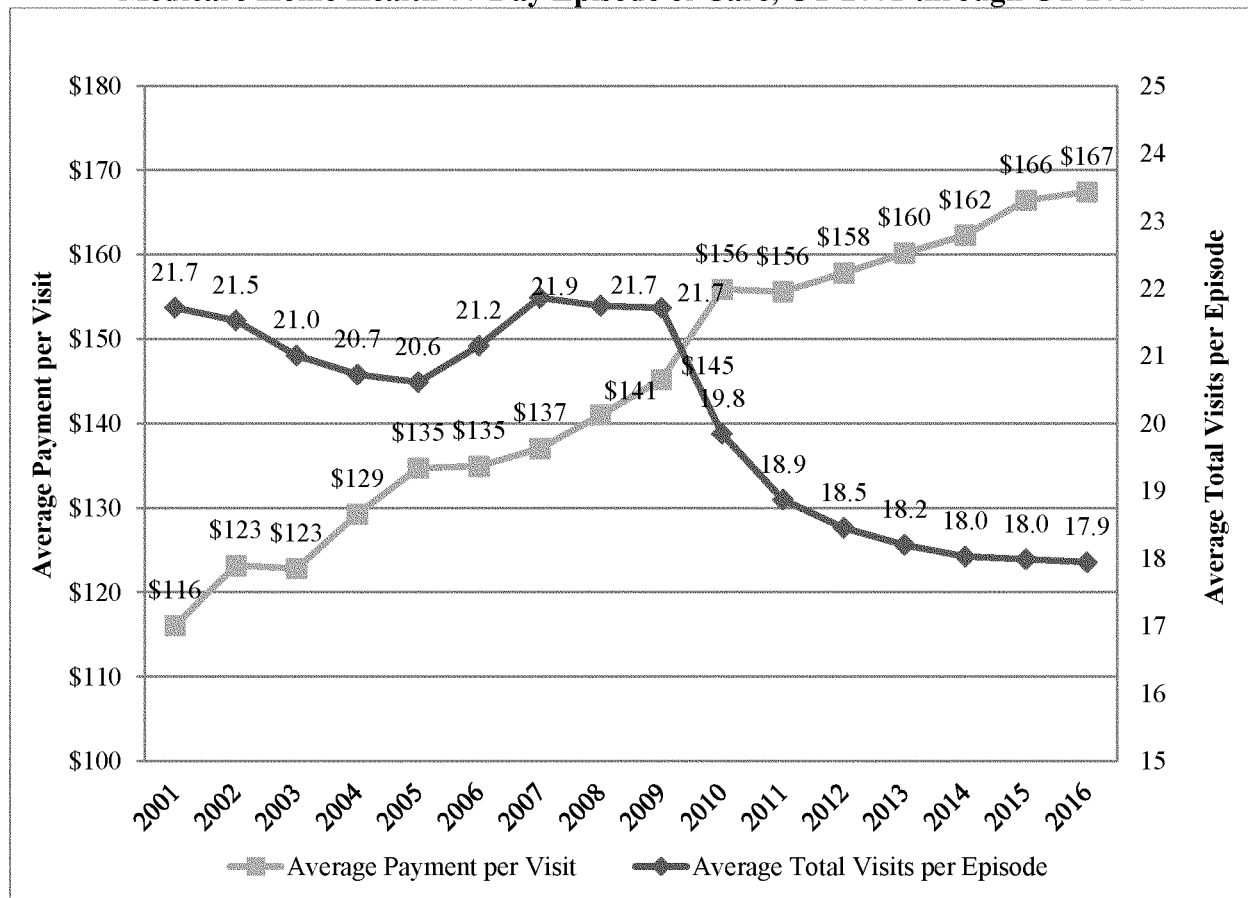
visits per 60-day episode of care and the average payment per visit. While the average payment per visit has steadily increased from approximately \$116 in CY 2001 to \$167 for CY 2016, the average total number of visits per 60-day episode of care has declined, most notably between CY 2009 (21.7 visits

per episode) and CY 2010 (19.8 visits per episode), which was the first year that the 10 percent agency-level cap on HHA outlier payments was implemented. The average of total visits per episode has steadily decreased from 21.7 in 2009 to 17.9 in 2016.

¹⁰ The data used for this table is not publicly available. Providers and researchers have access to similar data via the home health public use files at <https://www.cms.gov/Research-Statistics-Data-and->

[Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/HHA.html](https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/HHA.html) and through the CMS program statistics Web site at: <https://www.cms.gov/Research-Statistics-Data-and->

[Systems/Statistics-Trends-and-Reports/CMSProgramStatistics/index.html](https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMSProgramStatistics/index.html).

FIGURE 2: Average Total Number of Visits and Average Payment per Visit for a Medicare Home Health 60-Day Episode of Care, CY 2001 through CY 2016

Source: National claims history (NCH) data obtained from Chronic Condition Warehouse (CCW) – 2001 to 2014 data accessed on May 21, 2014, CY2015 data accessed on April 25, 2016, and CY2016 data accessed on March 16, 2017.

Note(s): These results exclude LUPA episodes, but include episodes from outlying areas (outside of 50 States and District of Columbia). Only episodes with a through date in the year specified are included. Episodes with a claim frequency code equal to "0" ("Non-payment/zero claims") and "2" ("Interim - first claim") are excluded. If a beneficiary is treated by providers from multiple states within a year the beneficiary is counted within each state's unique number of beneficiaries served.

Figure 3 displays the average number of visits by discipline type for a 60-day episode of care and shows that the number of therapy visits per 60-day episode of care has increased steadily. However, the number of skilled nursing visits has decreased from 10.7 in 2009 to 8.7 in 2016. The number of home health aide visits has decreased from 5.6

average visits in 2009 to 1.5 visits in 2016. The results of the home health study required by section 3131(d) of the Affordable Care Act suggest that the current home health payment system may discourage HHAs from serving patients with clinically complex and/or poorly controlled chronic conditions who do not qualify for therapy but

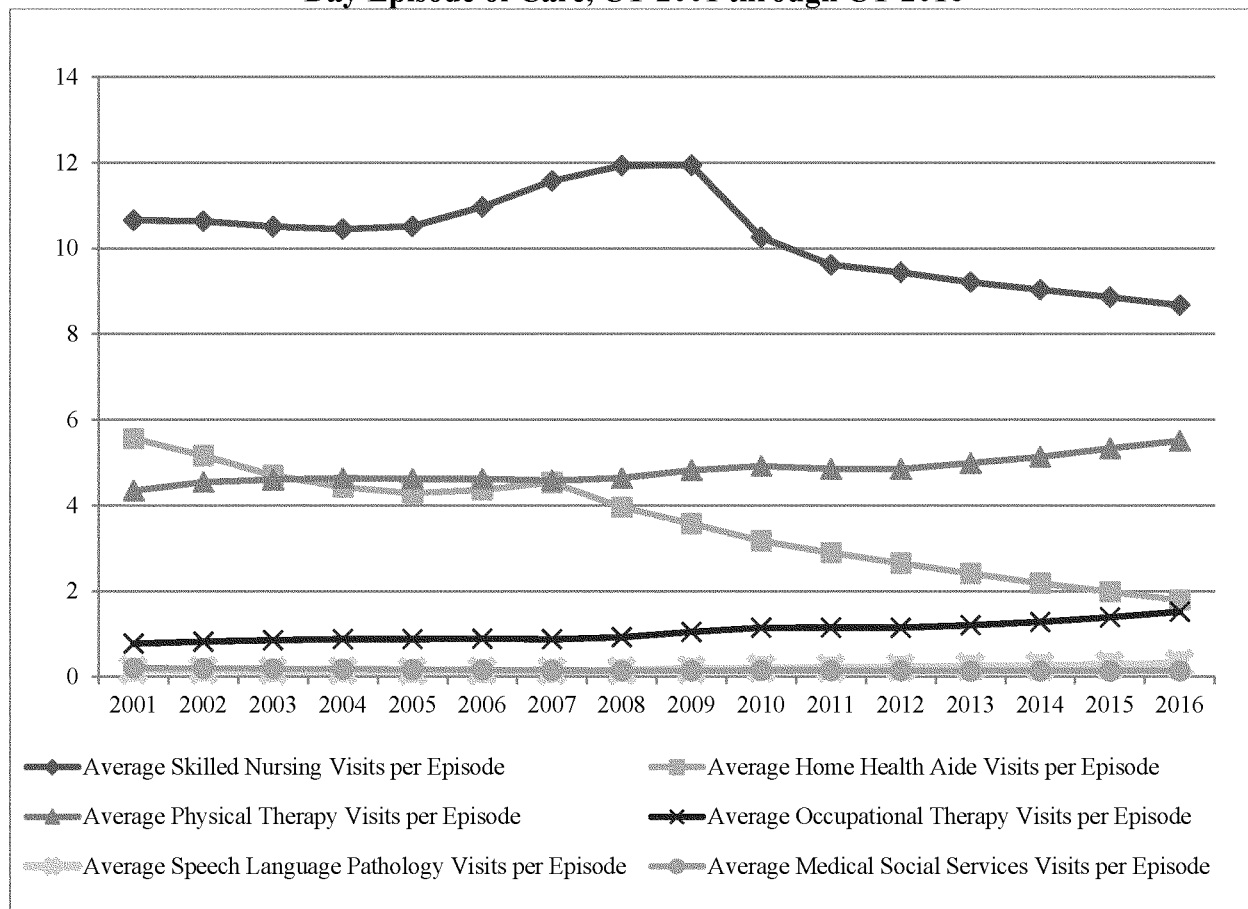
require a large number of skilled nursing visits.¹¹ The home health study results seem to be consistent with the recent trend in the decreased number of visits per episode of care driven by decreases in skilled nursing and home health aide services evident in Figures 2 and 3.

¹¹ The Report to Congress on the Home Health Study required by Section 3131(d) is available at

[https://www.cms.gov/Medicare/Medicare-Fee-for-](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Downloads/HH-Report-to-Congress.pdf)

[Service-Payment/HomeHealthPPS/Downloads/HH-Report-to-Congress.pdf](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Downloads/HH-Report-to-Congress.pdf).

FIGURE 3: Average Number of Visits by Discipline Type for a Medicare Home Health 60-Day Episode of Care, CY 2001 through CY 2016



Source: National claims history (NCH) data obtained from Chronic Condition Warehouse (CCW) - 2001 to 2014 data accessed on May 21, 2014, CY2015 data accessed on April 25, 2016, CY2016 data accessed on March 16, 2017.

Note(s): These results exclude LUPA episodes, but include episodes from outlying areas (outside of 50 States and District of Columbia). Only episodes with a through date in the year specified are included. Episodes with a claim frequency code equal to "0" ("Non-payment/zero claims") and "2" ("Interim - first claim") are excluded. If a beneficiary is treated by providers from multiple states within a year the beneficiary is counted within each state's unique number of beneficiaries served.

As part of our monitoring efforts, we also examined the trends in episode timing and service use over time. The first and second episodes are considered "early" episodes, while third and later episodes are considered "late" episodes. Specifically, we examined the percentage of early episodes with 0 to 19 therapy visits, late episodes with 0 to 19 therapy visits, and episodes with 20+ therapy visits from CY 2008 to CY 2016. In CY 2008, we implemented refinements to the HH PPS case-mix system. As part of those refinements, we added additional therapy thresholds and differentiated between early and late episodes for those episodes with

less than 20+ therapy visits. When the case-mix system first differentiated payments between early and late episodes of care, late episodes of care tended to have higher case-mix weights compared to early episodes of care. Table 4 shows that while there was a substantial increase in the number of late episodes between 2008 and 2009 (8 percentage points), since 2011 the number of late episodes as a percentage of total episodes has decreased over time. In 2015, the case-mix weights for the third and later episodes of care with 0 to 19 therapy visits decreased as a result of the CY 2015 recalibration of the case-mix weights. The recalibration of

the HH PPS case-mix weights, beginning in CY 2015, does not seem to have substantially impacted the percentage of early versus late episodes of care.

The case-mix weights for episodes with 20+ therapy visits are not determined based on the timing of the episode of care. The percentage of episodes with 20+ therapy visits increased from 4.6 percent in CY 2008 to 7.0 percent in CY 2016. The increase in the percentage of episodes with 20+ therapy visits is consistent with the overall observed increase in therapy visits provided during a 60-day episode of care (see Figure 3).

TABLE 4—HOME HEALTH EPISODES BY EPISODE TIMING, CY 2008 THROUGH CY 2016

Year	All episodes	Number of early episodes (excluding episodes with 20+ therapy visits)	% of early episodes (excluding episodes with 20+ therapy visits)	Number of late episodes (excluding episodes with 20+ therapy visits)	% of late episodes (excluding episodes with 20+ therapy visits)	Number of episodes with 20+ therapy visits	% of episodes with 20+ therapy visits
2008	5,423,037	3,571,619	65.9	1,600,587	29.5	250,831	4.6
2009	6,530,200	3,701,652	56.7	2,456,308	37.6	372,240	5.7
2010	6,877,598	3,872,504	56.3	2,586,493	37.6	418,601	6.1
2011	6,857,885	3,912,982	57.1	2,564,859	37.4	380,044	5.5
2012	6,767,576	3,955,207	58.4	2,458,734	36.3	353,635	5.2
2013	6,733,146	4,023,486	59.8	2,347,420	34.9	362,240	5.4
2014	6,616,875	3,980,151	60.2	2,263,638	34.2	373,086	5.6
2015	6,644,922	4,008,279	60.3	2,205,052	33.2	431,591	6.5
2016	6,294,232	3,802,254	60.4	2,053,972	32.6	438,006	7.0

SOURCE: National claims history (NCH) data obtained from Chronic Condition Warehouse (CCW)—Accessed on March 21, 2017.

NOTE(S): Only episodes with a through date in the year specified are included. Episodes with a claim frequency code equal to "0" ("Non-payment/zero claims") and "2" ("Interim—first claim") are excluded.

We also examined trends in admission source for home health episodes over time. Specifically, we examined the admission source for the "first or only" episodes of care (first episodes in a sequence of adjacent episodes of care or the only episode of care) from CY 2008 through CY 2016 (Figure 4). The percentage of first or only episodes with an acute admission source, defined as episodes with an inpatient hospital stay within the 14 days prior to a home health episode, has decreased from 38.6 percent in CY 2008 to 33.9 percent in CY 2016. The percentage of first or only episodes with

a post-acute admission source, defined as episodes which had a stay at a skilled nursing facility (SNF), inpatient rehabilitation facility (IRF), or long term care hospital (LTCH) within 14 days prior to the home health episode, slightly increased from 16.5 percent in CY 2008 to 17.5 percent in CY 2016. The percentage of first or only episodes with a community admission source, defined as episodes which did not have an acute or post-acute stay in the 14 days prior to the home health episode, increased from 37.4 percent in CY 2008 to 42.6 percent in CY 2016. Our findings on the trends in admission source are

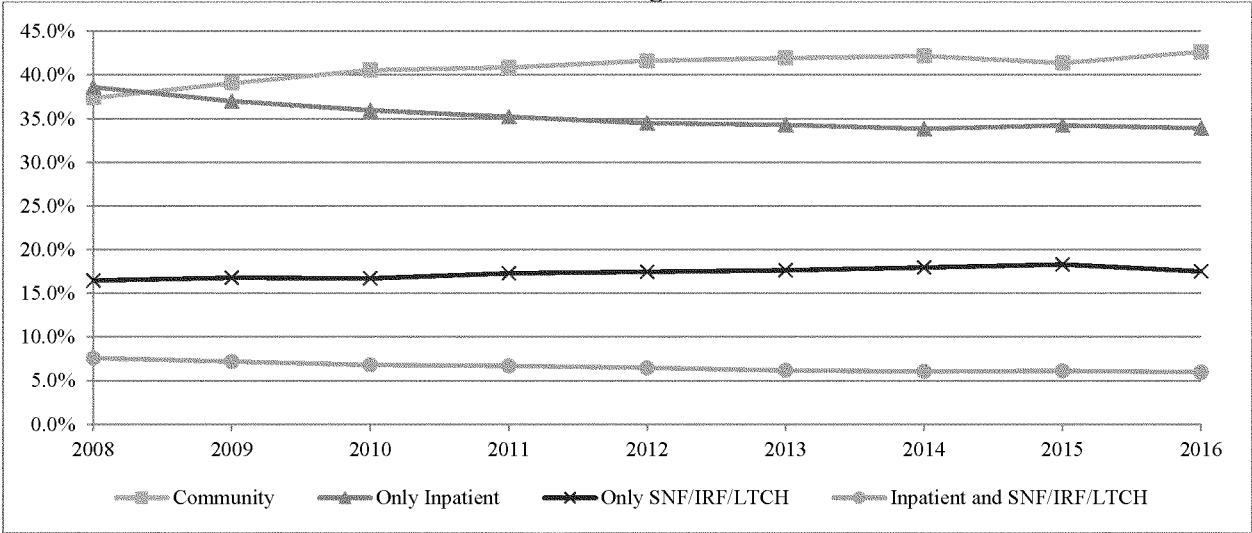
consistent with MedPAC's as outlined in their 2015 Report to the Congress.¹² MedPAC examined admission source trends from 2002 up through 2013 and concluded that "there has been tremendous growth in the use of home health for patients residing in the community, episodes not preceded by a prior hospitalization. The high rates of volume growth for these types of episodes, which have more than doubled since 2001, suggest there is significant potential for overuse, particularly since Medicare does not currently require any cost sharing for home health care."

¹² Medicare Payment Advisory Commission (MedPAC). "Home Health Care Services." *Report to the Congress: Medicare Payment Policy*.

Washington, DC, March 2015. P. 214. Accessed on 3/28/2017 at <http://www.medpac.gov/docs/default-source/reports/chapter-9-home-health-care-services-march-2015-report-.pdf?sfvrsn=0>.

[source/reports/chapter-9-home-health-care-services-march-2015-report-.pdf?sfvrsn=0](http://www.medpac.gov/docs/default-source/reports/chapter-9-home-health-care-services-march-2015-report-.pdf?sfvrsn=0).

FIGURE 4: Home Health Episode Trends by Admission Source (First or Only Episodes), CY 2008 through CY 2016



Source: National claims history (NCH) data obtained from Chronic Condition Warehouse (CCW) - Accessed on February 21, 2017.

Note(s): Only episodes with a through date in the year specified are included. Episodes with a claim frequency code equal to "0" ("Non-payment/zero claims") and "2" ("Interim - first claim") are excluded.

We will continue to monitor for potential impacts due to the rebasing adjustments required by section 3131(a) of the Affordable Care Act and other policy changes in the future. Independent effects of any one policy may be difficult to discern in years where multiple policy changes occur in any given year.

B. Proposed CY 2018 HH PPS Case-Mix Weights

In the CY 2015 HH PPS final rule (79 FR 66072), we finalized a policy to annually recalibrate the HH PPS case-mix weights—adjusting the weights relative to one another—using the most current, complete data available. To recalibrate the HH PPS case-mix weights for CY 2018, we will use the same methodology finalized in the CY 2008 HH PPS final rule (72 FR 49762), the CY

2012 HH PPS final rule (76 FR 68526), and the CY 2015 HH PPS final rule (79 FR 66032). Annual recalibration of the HH PPS case-mix weights ensures that the case-mix weights reflect, as accurately as possible, current home health resource use and changes in utilization patterns.

To generate the proposed CY 2018 HH PPS case-mix weights, we used CY 2016 home health claims data (as of March 17, 2017) with linked OASIS data. These data are the most current and complete data available at this time. We will use CY 2016 home health claims data (as of June 30, 2017 or later) with linked OASIS data to generate the CY 2018 HH PPS case-mix weights in the CY 2018 HH PPS final rule. The process we used to calculate the HH PPS case-mix weights are outlined below.

Step 1: Re-estimate the four-equation model to determine the clinical and functional points for an episode using wage-weighted minutes of care as our dependent variable for resource use. The wage-weighted minutes of care are determined using the CY 2015 Bureau of Labor Statistics national hourly wage plus fringe rates for the six home health disciplines and the minutes per visit from the claim. The points for each of the variables for each leg of the model, updated with CY 2016 home health claims data, are shown in Table 5. The points for the clinical variables are added together to determine an episode's clinical score. The points for the functional variables are added together to determine an episode's functional score.

TABLE 5.—CASE-MIX ADJUSTMENT VARIABLES AND SCORES

Episode number within sequence of adjacent episodes		1 or 2	1 or 2	3+	3+
Therapy visits		0–13	14+	0–13	14+
EQUATION:		1	2	3	4
CLINICAL DIMENSION					
1	Primary or Other Diagnosis = Blindness/Low Vision				
2	Primary or Other Diagnosis = Blood disorders		1		
3	Primary or Other Diagnosis = Cancer, selected benign neoplasms.		4		4
4	Primary Diagnosis = Diabetes		3		1
5	Other Diagnosis = Diabetes	1			
6	Primary or Other Diagnosis = Dysphagia AND Primary or Other Diagnosis = Neuro 3—Stroke.	2	16	1	10

TABLE 5.—CASE-MIX ADJUSTMENT VARIABLES AND SCORES—Continued

7	Primary or Other Diagnosis = Dysphagia AND M1030 (Therapy at home) = 3 (Enteral).	1	6		6
8	Primary or Other Diagnosis = Gastrointestinal disorders				2
9	Primary or Other Diagnosis = Gastrointestinal disorders AND M1630 (ostomy)= 1 or 2.		7		
10	Primary or Other Diagnosis = Gastrointestinal disorders AND Primary or Other Diagnosis = Neuro 1—Brain disorders and paralysis, OR Neuro 2—Peripheral neurological disorders, OR Neuro 3—Stroke, OR Neuro 4—Multiple Sclerosis.				
11	Primary or Other Diagnosis = Heart Disease OR Hypertension.	1	3		2
12	Primary Diagnosis = Neuro 1—Brain disorders and paralysis.	2	9	6	9
13	Primary or Other Diagnosis = Neuro 1—Brain disorders and paralysis AND M1840 (Toilet transfer) = 2 or more.		4		4
14	Primary or Other Diagnosis = Neuro 1—Brain disorders and paralysis OR Neuro 2—Peripheral neurological disorders AND M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3.	2	4	1	4
15	Primary or Other Diagnosis = Neuro 3—Stroke	3	9	2	4
16	Primary or Other Diagnosis = Neuro 3—Stroke AND M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3.		2		
17	Primary or Other Diagnosis = Neuro 3—Stroke AND M1860 (Ambulation) = 4 or more.				
18	Primary or Other Diagnosis = Neuro 4—Multiple Sclerosis AND AT LEAST ONE OF THE FOLLOWING: M1830 (Bathing) = 2 or more OR M1840 (Toilet transfer) = 2 or more OR M1850 (Transferring) = 2 or more OR M1860 (Ambulation) = 4 or more.	3	7	5	10
19	Primary or Other Diagnosis = Ortho 1—Leg Disorders or Gait Disorders AND M1324 (most problematic pressure ulcer stage)= 1, 2, 3 or 4.	7	1	7	
20	Primary or Other Diagnosis = Ortho 1—Leg OR Ortho 2—Other orthopedic disorders AND M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral).	3		3	7
21	Primary or Other Diagnosis = Psych 1—Affective and other psychoses, depression.				
22	Primary or Other Diagnosis = Psych 2—Degenerative and other organic psychiatric disorders.				
23	Primary or Other Diagnosis = Pulmonary disorders		2		1
24	Primary or Other Diagnosis = Pulmonary disorders AND M1860 (Ambulation) = 1 or more.				
25	Primary Diagnosis = Skin 1—Traumatic wounds, burns, and post-operative complications.	3	17	6	17
26	Other Diagnosis = Skin 1—Traumatic wounds, burns, post-operative complications.	6	13	8	13
27	Primary or Other Diagnosis = Skin 1—Traumatic wounds, burns, and post-operative complications OR Skin 2—Ulcers and other skin conditions AND M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral).	2			
28	Primary or Other Diagnosis = Skin 2—Ulcers and other skin conditions.	2	16	8	17
29	Primary or Other Diagnosis = Tracheostomy	2	17		17
30	Primary or Other Diagnosis = Urostomy/Cystostomy		17		12
31	M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral).		15	5	15
32	M1030 (Therapy at home) = 3 (Enteral)		15		8
33	M1200 (Vision) = 1 or more				
34	M1242 (Pain)= 3 or 4	3		2	
35	M1311 = Two or more pressure ulcers at stage 3 or 4	4	6	4	6
36	M1324 (Most problematic pressure ulcer stage)= 1 or 2	4	19	7	16
37	M1324 (Most problematic pressure ulcer stage)= 3 or 4	8	31	10	25
38	M1334 (Stasis ulcer status)= 2	4	13	7	13
39	M1334 (Stasis ulcer status)= 3	7	17	9	17
40	M1342 (Surgical wound status)= 2	2	7	6	13
41	M1342 (Surgical wound status)= 3		6	5	10
42	M1400 (Dyspnea) = 2, 3, or 4	1	1		
43	M1620 (Bowel Incontinence) = 2 to 5		3		2
44	M1630 (Ostomy)= 1 or 2	4	11	2	8
45	M2030 (Injectable Drug Use) = 0, 1, 2, or 3				

TABLE 5—CASE-MIX ADJUSTMENT VARIABLES AND SCORES—Continued

FUNCTIONAL DIMENSION					
46	M1810 or M1820 (Dressing upper or lower body) = 1, 2, or 3.	1			
47	M1830 (Bathing) = 2 or more	6	5	5	2
48	M1840 (Toilet transferring) = 2 or more		1		
49	M1850 (Transferring) = 2 or more	3	1	2	
50	M1860 (Ambulation) = 1, 2 or 3	7		4	
51	M1860 (Ambulation) = 4 or more	8	9	6	7

Source: CY 2016 Medicare claims data for episodes ending on or before December 31, 2016 (as of December 31, 2016) for which we had a linked OASIS assessment. LUPA episodes, outlier episodes, and episodes with PEP adjustments were excluded.

Note(s): Points are additive; however, points may not be given for the same line item in the table more than once. Please see Medicare Home Health Diagnosis Coding guidance at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/coding_billing.html for definitions of primary and secondary diagnoses.

In updating the four-equation model for CY 2018, using 2016 home health claims data (the last update to the four-equation model for CY 2017 used CY 2015 home health claims data), there were few changes to the point values for the variables in the four-equation model. These relatively minor changes reflect the change in the relationship between the grouper variables and resource use between CY 2015 and CY 2016. The CY 2018 four-equation model resulted in 120 point-giving variables being used in the model (as compared to the 124 variables for the CY 2017 recalibration). There were 8 variables that were added to the model and 12 variables that were dropped from the model due to the absence of additional resources associated with the variable. Of the variables that were in both the four-equation model for CY 2017 and the four-equation model for CY 2018, the points for 14 variables increased in the CY 2018 four-equation model and

the points for 48 variables decreased in the CY 2018 4-equation model. There were 50 variables with the same point values.

Step 2: Re-defining the clinical and functional thresholds so they are reflective of the new points associated with the CY 2018 four-equation model. After estimating the points for each of the variables and summing the clinical and functional points for each episode, we look at the distribution of the clinical score and functional score, breaking the episodes into different steps. The categorizations for the steps are as follows:

- Step 1: First and second episodes, 0–13 therapy visits.
- Step 2.1: First and second episodes, 14–19 therapy visits.
- Step 2.2: Third episodes and beyond, 14–19 therapy visits.
- Step 3: Third episodes and beyond, 0–13 therapy visits.
- Step 4: Episodes with 20+ therapy visits.

We then divide the distribution of the clinical score for episodes within a step such that a third of episodes are classified as low clinical score, a third of episodes are classified as medium clinical score, and a third of episodes are classified as high clinical score. The same approach is then done looking at the functional score. It was not always possible to evenly divide the episodes within each step into thirds due to many episodes being clustered around one particular score.¹³ Also, we looked at the average resource use associated with each clinical and functional score and used that as a guide for setting our thresholds. We grouped scores with similar average resource use within the same level (even if it meant that more or less than a third of episodes were placed within a level). The new thresholds, based off the CY 2018 four-equation model points are shown in Table 6.

TABLE 6—CY 2018 CLINICAL AND FUNCTIONAL THRESHOLDS

		1st and 2nd episodes		3rd+ episodes		All Episodes
		0 to 13 therapy visits	14 to 19 therapy visits	0 to 13 therapy visits	14 to 19 therapy visits	20+ therapy visits
Grouping Step		1	2	3	4	5
Equations used to calculate points (see Table B1)		1	2	3	4	(2&4)
Dimension	Severity Level					
Clinical	C1	0 to 1	0 to 1	0 to 1	0 to 1	0 to 3
	C2	2 to 3	2 to 7	2	2 to 9	4 to 16
	C3	4+	8+	3+	10+	17+
Functional	F1	0 to 13	0 to 7	0 to 6	0 to 2	0 to 2
	F2	14	8 to 15	7 to 10	3 to 7	3 to 6
	F3	15+	16+	11+	8+	7+

¹³ For Step 1, 45.4% of episodes were in the medium functional level (All with score 14).

For Step 2.1, 87.3% of episodes were in the low functional level (Most with scores 5 to 7).

For Step 2.2, 81.9% of episodes were in the low functional level (Most with score 1).

For Step 3, 46.4% of episodes were in the medium functional level (Most with score 9).

For Step 4, 48.6% of episodes were in the medium functional level (Most with score 5 or 6).

Step 3: Once the clinical and functional thresholds are determined and each episode is assigned a clinical and functional level, the payment regression is estimated with an episode's wage-weighted minutes of care as the dependent variable. Independent variables in the model are

indicators for the step of the episode as well as the clinical and functional levels within each step of the episode. Like the four-equation model, the payment regression model is also estimated with robust standard errors that are clustered at the beneficiary level. Table 7 shows the regression coefficients for the

variables in the payment regression model updated with CY 2016 home health claims data. The R-squared value for the payment regression model is 0.5073 (an increase from 0.4919 for the CY 2017 recalibration).

TABLE 7—PAYMENT REGRESSION MODEL

	Payment regression from 4-equation model for CY2018
Step 1, Clinical Score Medium	\$24.35
Step 1, Clinical Score High	54.10
Step 1, Functional Score Medium	71.10
Step 1, Functional Score High	104.74
Step 2.1, Clinical Score Medium	47.79
Step 2.1, Clinical Score High	133.50
Step 2.1, Functional Score Medium	30.46
Step 2.1, Functional Score High	55.93
Step 2.2, Clinical Score Medium	39.93
Step 2.2, Clinical Score High	192.15
Step 2.2, Functional Score Medium	17.99
Step 2.2, Functional Score High	53.34
Step 3, Clinical Score Medium	14.03
Step 3, Clinical Score High	92.83
Step 3, Functional Score Medium	56.27
Step 3, Functional Score High	86.76
Step 4, Clinical Score Medium	78.75
Step 4, Clinical Score High	260.68
Step 4, Functional Score Medium	25.95
Step 4, Functional Score High	58.66
Step 2.1, 1st and 2nd Episodes, 14 to 19 Therapy Visits	497.79
Step 2.2, 3rd+ Episodes, 14 to 19 Therapy Visits	508.40
Step 3, 3rd+ Episodes, 0–13 Therapy Visits	–67.30
Step 4, All Episodes, 20+ Therapy Visits	883.46
Intercept	382.25

Source: CY 2016 Medicare claims data for episodes ending on or before December 31, 2016 (as of March 17, 2017) for which we had a linked OASIS assessment.

Step 4: We use the coefficients from the payment regression model to predict each episode's wage-weighted minutes of care (resource use). We then divide these predicted values by the mean of the dependent variable (that is, the average wage-weighted minutes of care across all episodes used in the payment regression). This division constructs the weight for each episode, which is simply the ratio of the episode's predicted wage-weighted minutes of care divided by the average wage-weighted minutes of care in the sample. Each episode is then aggregated into one of the 153 home health resource groups (HHRGs) and the "raw" weight for each HHRG was calculated as the average of the episode weights within the HHRG.

Step 5: The raw weights associated with 0 to 5 therapy visits are then

increased by 3.75 percent, the weights associated with 14–15 therapy visits are decreased by 2.5 percent, and the weights associated with 20+ therapy visits are decreased by 5 percent. These adjustments to the case-mix weights were finalized in the CY 2012 HH PPS final rule (76 FR 68557) and were done to address MedPAC's concerns that the HH PPS overvalues therapy episodes and undervalues non-therapy episodes and to better align the case-mix weights with episode costs estimated from cost report data.¹⁴

Step 6: After the adjustments in Step 5 are applied to the raw weights, the weights are further adjusted to create an increase in the payment weights for the therapy visit steps between the therapy thresholds. Weights with the same clinical severity level, functional

severity level, and early/late episode status were grouped together. Then within those groups, the weights for each therapy step between thresholds are gradually increased. We do this by interpolating between the main thresholds on the model (from 0–5 to 14–15 therapy visits, and from 14–15 to 20+ therapy visits). We use a linear model to implement the interpolation so the payment weight increase for each step between the thresholds (such as the increase between 0–5 therapy visits and 6 therapy visits and the increase between 6 therapy visits and 7–9 therapy visits) are constant. This interpolation is identical to the process finalized in the CY 2012 HH PPS final rule (76 FR 68555).

Step 7: The interpolated weights are then adjusted so that the average case-

¹⁴ Medicare Payment Advisory Commission (MedPAC), *Report to the Congress: Medicare Payment Policy*. March 2011, P. 176.

¹⁵ When computing the average, we compute a weighted average, assigning a value of one to each

normal episode and a value equal to the episode length divided by 60 for PEPs.

mix for the weights is equal to 1.0000.¹⁵ 2018 case-mix weights shown in Table
This last step creates the proposed CY 8.

TABLE 8—PROPOSED CY 2018 CASE-MIX PAYMENT WEIGHTS

Pay group	Description	Clinical and functional levels (1 = low; 2 = medium; 3 = high)	Proposed CY 2018 weight
10111	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F1S1	0.5617
10112	1st and 2nd Episodes, 6 Therapy Visits	C1F1S2	0.6925
10113	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F1S3	0.8232
10114	1st and 2nd Episodes, 10 Therapy Visits	C1F1S4	0.9539
10115	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F1S5	1.0846
10121	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F2S1	0.6662
10122	1st and 2nd Episodes, 6 Therapy Visits	C1F2S2	0.7845
10123	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F2S3	0.9027
10124	1st and 2nd Episodes, 10 Therapy Visits	C1F2S4	1.0209
10125	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F2S5	1.1392
10131	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F3S1	0.7157
10132	1st and 2nd Episodes, 6 Therapy Visits	C1F3S2	0.8311
10133	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F3S3	0.9464
10134	1st and 2nd Episodes, 10 Therapy Visits	C1F3S4	1.0618
10135	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F3S5	1.1772
10211	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F1S1	0.5975
10212	1st and 2nd Episodes, 6 Therapy Visits	C2F1S2	0.7343
10213	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F1S3	0.8711
10214	1st and 2nd Episodes, 10 Therapy Visits	C2F1S4	1.0078
10215	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F1S5	1.1446
10221	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F2S1	0.7020
10222	1st and 2nd Episodes, 6 Therapy Visits	C2F2S2	0.8263
10223	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F2S3	0.9506
10224	1st and 2nd Episodes, 10 Therapy Visits	C2F2S4	1.0749
10225	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F2S5	1.1991
10231	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F3S1	0.7514
10232	1st and 2nd Episodes, 6 Therapy Visits	C2F3S2	0.8729
10233	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F3S3	0.9943
10234	1st and 2nd Episodes, 10 Therapy Visits	C2F3S4	1.1157
10235	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F3S5	1.2372
10311	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F1S1	0.6412
10312	1st and 2nd Episodes, 6 Therapy Visits	C3F1S2	0.7929
10313	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F1S3	0.9446
10314	1st and 2nd Episodes, 10 Therapy Visits	C3F1S4	1.0963
10315	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F1S5	1.2480
10321	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F2S1	0.7457
10322	1st and 2nd Episodes, 6 Therapy Visits	C3F2S2	0.8850
10323	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F2S3	1.0242
10324	1st and 2nd Episodes, 10 Therapy Visits	C3F2S4	1.1634
10325	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F2S5	1.3026
10331	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F3S1	0.7952
10332	1st and 2nd Episodes, 6 Therapy Visits	C3F3S2	0.9315
10333	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F3S3	1.0679
10334	1st and 2nd Episodes, 10 Therapy Visits	C3F3S4	1.2043
10335	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F3S5	1.3406
21111	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F1S1	1.2154
21112	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F1S2	1.3780
21113	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F1S3	1.5406
21121	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F2S1	1.2574
21122	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F2S2	1.4176
21123	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F2S3	1.5779
21131	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F3S1	1.2926
21132	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F3S2	1.4558
21133	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F3S3	1.6189
21211	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F1S1	1.2814
21212	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F1S2	1.4573
21213	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F1S3	1.6332
21221	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F2S1	1.3234
21222	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F2S2	1.4970
21223	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F2S3	1.6705
21231	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F3S1	1.3586
21232	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F3S2	1.5351

¹⁵ When computing the average, we compute a weighted average, assigning a value of one to each

normal episode and a value equal to the episode length divided by 60 for PEPs.

TABLE 8—PROPOSED CY 2018 CASE-MIX PAYMENT WEIGHTS—Continued

Pay group	Description	Clinical and functional levels (1 = low; 2 = medium; 3 = high)	Proposed CY 2018 weight
21233	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F3S3	1.7116
21311	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F1S1	1.3997
21312	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F1S2	1.6178
21313	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F1S3	1.8359
21321	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F2S1	1.4418
21322	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F2S2	1.6575
21323	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F2S3	1.8732
21331	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F3S1	1.4770
21332	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F3S2	1.6956
21333	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F3S3	1.9142
22111	3rd+ Episodes, 14 to 15 Therapy Visits	C1F1S1	1.2300
22112	3rd+ Episodes, 16 to 17 Therapy Visits	C1F1S2	1.3877
22113	3rd+ Episodes, 18 to 19 Therapy Visits	C1F1S3	1.5455
22121	3rd+ Episodes, 14 to 15 Therapy Visits	C1F2S1	1.2549
22122	3rd+ Episodes, 16 to 17 Therapy Visits	C1F2S2	1.4159
22123	3rd+ Episodes, 18 to 19 Therapy Visits	C1F2S3	1.5770
22131	3rd+ Episodes, 14 to 15 Therapy Visits	C1F3S1	1.3037
22132	3rd+ Episodes, 16 to 17 Therapy Visits	C1F3S2	1.4632
22133	3rd+ Episodes, 18 to 19 Therapy Visits	C1F3S3	1.6226
22211	3rd+ Episodes, 14 to 15 Therapy Visits	C2F1S1	1.2852
22212	3rd+ Episodes, 16 to 17 Therapy Visits	C2F1S2	1.4598
22213	3rd+ Episodes, 18 to 19 Therapy Visits	C2F1S3	1.6345
22221	3rd+ Episodes, 14 to 15 Therapy Visits	C2F2S1	1.3100
22222	3rd+ Episodes, 16 to 17 Therapy Visits	C2F2S2	1.4880
22223	3rd+ Episodes, 18 to 19 Therapy Visits	C2F2S3	1.6660
22231	3rd+ Episodes, 14 to 15 Therapy Visits	C2F3S1	1.3588
22232	3rd+ Episodes, 16 to 17 Therapy Visits	C2F3S2	1.5352
22233	3rd+ Episodes, 18 to 19 Therapy Visits	C2F3S3	1.7117
22311	3rd+ Episodes, 14 to 15 Therapy Visits	C3F1S1	1.4954
22312	3rd+ Episodes, 16 to 17 Therapy Visits	C3F1S2	1.6816
22313	3rd+ Episodes, 18 to 19 Therapy Visits	C3F1S3	1.8678
22321	3rd+ Episodes, 14 to 15 Therapy Visits	C3F2S1	1.5202
22322	3rd+ Episodes, 16 to 17 Therapy Visits	C3F2S2	1.7098
22323	3rd+ Episodes, 18 to 19 Therapy Visits	C3F2S3	1.8993
22331	3rd+ Episodes, 14 to 15 Therapy Visits	C3F3S1	1.5690
22332	3rd+ Episodes, 16 to 17 Therapy Visits	C3F3S2	1.7570
22333	3rd+ Episodes, 18 to 19 Therapy Visits	C3F3S3	1.9449
30111	3rd+ Episodes, 0 to 5 Therapy Visits	C1F1S1	0.4628
30112	3rd+ Episodes, 6 Therapy Visits	C1F1S2	0.6163
30113	3rd+ Episodes, 7 to 9 Therapy Visits	C1F1S3	0.7697
30114	3rd+ Episodes, 10 Therapy Visits	C1F1S4	0.9232
30115	3rd+ Episodes, 11 to 13 Therapy Visits	C1F1S5	1.0766
30121	3rd+ Episodes, 0 to 5 Therapy Visits	C1F2S1	0.5455
30122	3rd+ Episodes, 6 Therapy Visits	C1F2S2	0.6874
30123	3rd+ Episodes, 7 to 9 Therapy Visits	C1F2S3	0.8293
30124	3rd+ Episodes, 10 Therapy Visits	C1F2S4	0.9711
30125	3rd+ Episodes, 11 to 13 Therapy Visits	C1F2S5	1.1130
30131	3rd+ Episodes, 0 to 5 Therapy Visits	C1F3S1	0.5903
30132	3rd+ Episodes, 6 Therapy Visits	C1F3S2	0.7330
30133	3rd+ Episodes, 7 to 9 Therapy Visits	C1F3S3	0.8757
30134	3rd+ Episodes, 10 Therapy Visits	C1F3S4	1.0183
30135	3rd+ Episodes, 11 to 13 Therapy Visits	C1F3S5	1.1610
30211	3rd+ Episodes, 0 to 5 Therapy Visits	C2F1S1	0.4835
30212	3rd+ Episodes, 6 Therapy Visits	C2F1S2	0.6438
30213	3rd+ Episodes, 7 to 9 Therapy Visits	C2F1S3	0.8041
30214	3rd+ Episodes, 10 Therapy Visits	C2F1S4	0.9645
30215	3rd+ Episodes, 11 to 13 Therapy Visits	C2F1S5	1.1248
30221	3rd+ Episodes, 0 to 5 Therapy Visits	C2F2S1	0.5662
30222	3rd+ Episodes, 6 Therapy Visits	C2F2S2	0.7149
30223	3rd+ Episodes, 7 to 9 Therapy Visits	C2F2S3	0.8637
30224	3rd+ Episodes, 10 Therapy Visits	C2F2S4	1.0125
30225	3rd+ Episodes, 11 to 13 Therapy Visits	C2F2S5	1.1612
30231	3rd+ Episodes, 0 to 5 Therapy Visits	C2F3S1	0.6110
30232	3rd+ Episodes, 6 Therapy Visits	C2F3S2	0.7605
30233	3rd+ Episodes, 7 to 9 Therapy Visits	C2F3S3	0.9101
30234	3rd+ Episodes, 10 Therapy Visits	C2F3S4	1.0597
30235	3rd+ Episodes, 11 to 13 Therapy Visits	C2F3S5	1.2093
30311	3rd+ Episodes, 0 to 5 Therapy Visits	C3F1S1	0.5993

TABLE 8—PROPOSED CY 2018 CASE-MIX PAYMENT WEIGHTS—Continued

Pay group	Description	Clinical and functional levels (1 = low; 2 = medium; 3 = high)	Proposed CY 2018 weight
30312	3rd+ Episodes, 6 Therapy Visits	C3F1S2	0.7785
30313	3rd+ Episodes, 7 to 9 Therapy Visits	C3F1S3	0.9577
30314	3rd+ Episodes, 10 Therapy Visits	C3F1S4	1.1369
30315	3rd+ Episodes, 11 to 13 Therapy Visits	C3F1S5	1.3162
30321	3rd+ Episodes, 0 to 5 Therapy Visits	C3F2S1	0.6820
30322	3rd+ Episodes, 6 Therapy Visits	C3F2S2	0.8496
30323	3rd+ Episodes, 7 to 9 Therapy Visits	C3F2S3	1.0173
30324	3rd+ Episodes, 10 Therapy Visits	C3F2S4	1.1849
30325	3rd+ Episodes, 11 to 13 Therapy Visits	C3F2S5	1.3526
30331	3rd+ Episodes, 0 to 5 Therapy Visits	C3F3S1	0.7268
30332	3rd+ Episodes, 6 Therapy Visits	C3F3S2	0.8952
30333	3rd+ Episodes, 7 to 9 Therapy Visits	C3F3S3	1.0637
30334	3rd+ Episodes, 10 Therapy Visits	C3F3S4	1.2321
30335	3rd+ Episodes, 11 to 13 Therapy Visits	C3F3S5	1.4006
40111	All Episodes, 20+ Therapy Visits	C1F1S1	1.7032
40121	All Episodes, 20+ Therapy Visits	C1F2S1	1.7381
40131	All Episodes, 20+ Therapy Visits	C1F3S1	1.7821
40211	All Episodes, 20+ Therapy Visits	C2F1S1	1.8091
40221	All Episodes, 20+ Therapy Visits	C2F2S1	1.8440
40231	All Episodes, 20+ Therapy Visits	C2F3S1	1.8881
40311	All Episodes, 20+ Therapy Visits	C3F1S1	2.0539
40321	All Episodes, 20+ Therapy Visits	C3F2S1	2.0889
40331	All Episodes, 20+ Therapy Visits	C3F3S1	2.1329

To ensure the changes to the HH PPS case-mix weights are implemented in a budget neutral manner, we then apply a case-mix budget neutrality factor to the proposed CY 2018 national, standardized 60-day episode payment rate (see section III.C.3. of this proposed rule). The case-mix budget neutrality factor is calculated as the ratio of total payments when the CY 2018 HH PPS case-mix weights (developed using CY 2016 home health claims data) are applied to CY 2016 utilization (claims) data to total payments when CY 2017 HH PPS case-mix weights (developed using CY 2015 home health claims data) are applied to CY 2016 utilization data. This produces a case-mix budget neutrality factor for CY 2018 of 1.0159.

C. Proposed CY 2018 Home Health Payment Rate Update

1. Proposed CY 2018 Home Health Market Basket Update

Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts for CY 2018 be increased by a factor equal to the applicable HH market basket update for those HHAs that submit quality data as required by the Secretary. The home health market basket was rebased and revised in CY 2013. A detailed description of how we derive the HHA market basket is available in the CY 2013 HH PPS final rule (77 FR 67080 through 67090).

Section 1895(b)(3)(B)(vi) of the Act, requires that, in CY 2015 (and in subsequent calendar years, except CY 2018 (under section 411(c) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted April 16, 2015)), the market basket percentage under the HHA prospective payment system as described in section 1895(b)(3)(B) of the Act be annually adjusted by changes in economy-wide productivity. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment to be equal to the 10-year moving average of change in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period) (the “MFP adjustment”). The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private nonfarm business MFP. Please see <http://www.bls.gov/mfp>, to obtain the BLS historical published MFP data.

Prior to the enactment of the MACRA, which amended section 1895(b)(3)(B) of the Act, the proposed home health update percentage for CY 2018 would have been based on the estimated home health market basket update of 2.7 percent (based on IHS Global Insight Inc.’s first-quarter 2017 forecast with

historical data through fourth-quarter 2016). Due to the requirements specified at section 1895(b)(3)(B)(vi) of the Act prior to the enactment of MACRA, the estimated CY 2018 home health market basket update of 2.7 percent would have been reduced by a MFP adjustment as mandated by the Affordable Care Act (currently estimated to be 0.5 percentage point for CY 2018). In effect, the proposed home health payment update percentage for CY 2018 would have been 2.2 percent. However, section 411(c) of the MACRA amended section 1895(b)(3)(B) of the Act, such that for home health payments for CY 2018, the market basket percentage increase is required to be 1 percent.

Section 1895(b)(3)(B) of the Act requires that the home health update be decreased by 2 percentage points for those HHAs that do not submit quality data as required by the Secretary. For HHAs that do not submit the required quality data for CY 2018, the home health payment update would be -1 percent (1 percent minus 2 percentage points).

2. Proposed CY 2018 Home Health Wage Index

Sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act require the Secretary to provide appropriate adjustments to the proportion of the payment amount under the HH PPS that account for area wage differences, using adjustment

factors that reflect the relative level of wages and wage-related costs applicable to the furnishing of HH services. Since the inception of the HH PPS, we have used inpatient hospital wage data in developing a wage index to be applied to HH payments. We propose to continue this practice for CY 2018, as we continue to believe that, in the absence of HH-specific wage data, using inpatient hospital wage data is appropriate and reasonable for the HH PPS. Specifically, we propose to continue to use the pre-floor, pre-reclassified hospital wage index as the wage adjustment to the labor portion of the HH PPS rates. For CY 2018, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2013, and before October 1, 2014 (FY 2014 cost report data). We would apply the appropriate wage index value to the labor portion of the HH PPS rates based on the site of service for the beneficiary (defined by section 1861(m) of the Act as the beneficiary's place of residence).

To address those geographic areas in which there are no inpatient hospitals, and thus, no hospital wage data on which to base the calculation of the CY 2018 HH PPS wage index, we propose to continue to use the same methodology discussed in the CY 2007 HH PPS final rule (71 FR 65884) to address those geographic areas in which there are no inpatient hospitals. For rural areas that do not have inpatient hospitals, we would use the average wage index from all contiguous Core Based Statistical Areas (CBSAs) as a reasonable proxy. Currently, the only rural area without a hospital from which hospital wage data could be derived is Puerto Rico. However, for rural Puerto Rico, we would not apply this methodology due to the distinct economic circumstances that exist there (for example, due to the close proximity to one another of almost all of Puerto Rico's various urban and non-urban areas, this methodology would produce a wage index for rural Puerto Rico that is higher than that in half of its urban areas). Instead, we would continue to use the most recent wage index previously available for that area. For urban areas without inpatient hospitals, we would use the average wage index of all urban areas within the state as a reasonable proxy for the wage index for that CBSA. For CY 2018, the only urban area without inpatient hospital wage data is Hinesville, GA (CBSA 25980).

On February 28, 2013, OMB issued Bulletin No. 13-01, announcing revisions to the delineations of MSAs, Micropolitan Statistical Areas, and CBSAs, and guidance on uses of the

delineation of these areas. In the CY 2015 HH PPS final rule (79 FR 66085 through 66087), we adopted the OMB's new area delineations using a 1-year transition. The most recent bulletin (No. 15-01) concerning the revised delineations was published by the OMB on July 15, 2015.

The proposed CY 2018 wage index is available on the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices.html>.

3. Proposed CY 2018 Annual Payment Update

a. Background

The Medicare HH PPS has been in effect since October 1, 2000. As set forth in the July 3, 2000 final rule (65 FR 41128), the base unit of payment under the Medicare HH PPS is a national, standardized 60-day episode payment rate. As set forth in § 484.220, we adjust the national, standardized 60-day episode payment rate by a case-mix relative weight and a wage index value based on the site of service for the beneficiary.

To provide appropriate adjustments to the proportion of the payment amount under the HH PPS to account for area wage differences, we apply the appropriate wage index value to the labor portion of the HH PPS rates. The labor-related share of the case-mix adjusted 60-day episode rate would continue to be 78.535 percent and the non-labor-related share would continue to be 21.465 percent as set out in the CY 2013 HH PPS final rule (77 FR 67068). The CY 2018 HH PPS rates would use the same case-mix methodology as set forth in the CY 2008 HH PPS final rule with comment period (72 FR 49762) and would be adjusted as described in section III.B of this rule. The following are the steps we take to compute the case-mix and wage-adjusted 60-day episode rate:

(1) Multiply the national 60-day episode rate by the patient's applicable case-mix weight.

(2) Divide the case-mix adjusted amount into a labor (78.535 percent) and a non-labor portion (21.465 percent).

(3) Multiply the labor portion by the applicable wage index based on the site of service of the beneficiary.

(4) Add the wage-adjusted portion to the non-labor portion, yielding the case-mix and wage adjusted 60-day episode rate, subject to any additional applicable adjustments.

In accordance with section 1895(b)(3)(B) of the Act, this document

proposes the annual update of the HH PPS rates. Section 484.225 sets forth the specific annual percentage update methodology. In accordance with § 484.225(i), for a HHA that does not submit HH quality data, as specified by the Secretary, the unadjusted national prospective 60-day episode rate is equal to the rate for the previous calendar year increased by the applicable HH market basket index amount minus 2 percentage points. Any reduction of the percentage change would apply only to the calendar year involved and would not be considered in computing the prospective payment amount for a subsequent calendar year.

Medicare pays the national, standardized 60-day case-mix and wage-adjusted episode payment on a split percentage payment approach. The split percentage payment approach includes an initial percentage payment and a final percentage payment as set forth in § 484.205(b)(1) and (b)(2). We may base the initial percentage payment on the submission of a request for anticipated payment (RAP) and the final percentage payment on the submission of the claim for the episode, as discussed in § 409.43. The claim for the episode that the HHA submits for the final percentage payment determines the total payment amount for the episode and whether we make an applicable adjustment to the 60-day case-mix and wage-adjusted episode payment. The end date of the 60-day episode as reported on the claim determines which calendar year rates Medicare would use to pay the claim.

We may also adjust the 60-day case-mix and wage-adjusted episode payment based on the information submitted on the claim to reflect the following:

- A low-utilization payment adjustment (LUPA) is provided on a per-visit basis as set forth in §§ 484.205(c) and 484.230.
- A partial episode payment (PEP) adjustment as set forth in §§ 484.205(d) and 484.235.
- An outlier payment as set forth in §§ 484.205(e) and 484.240.

b. Proposed CY 2018 National, Standardized 60-Day Episode Payment Rate

Section 1895(3)(A)(i) of the Act requires that the 60-day episode base rate and other applicable amounts be standardized in a manner that eliminates the effects of variations in relative case-mix and area wage adjustments among different home health agencies in a budget neutral manner. To determine the CY 2018 national, standardized 60-day episode payment rate, we would apply a wage

index budget neutrality factor; a case-mix budget neutrality factor described in section III.B. of this proposed rule; a reduction of 0.97 percent to account for nominal case-mix growth from 2012 to 2014, as finalized in the CY 2016 HH PPS final rule (80 FR 68646); and the home health payment update percentage discussed in section III.C.1 of this proposed rule.

To calculate the wage index budget neutrality factor, we simulated total payments for non-LUPA episodes using the proposed CY 2018 wage index and compared it to our simulation of total payments for non-LUPA episodes using the CY 2017 wage index. By dividing the total payments for non-LUPA episodes using the proposed CY 2018 wage index by the total payments for

non-LUPA episodes using the CY 2017 wage index, we obtain a wage index budget neutrality factor of 1.0001. We would apply the wage index budget neutrality factor of 1.0001 to the calculation of the proposed CY 2018 national, standardized 60-day episode rate.

As discussed in section III.B. of this proposed rule, to ensure the changes to the case-mix weights are implemented in a budget neutral manner, we would apply a case-mix weight budget neutrality factor to the CY 2018 national, standardized 60-day episode payment rate. The case-mix weight budget neutrality factor is calculated as the ratio of total payments when CY 2018 case-mix weights are applied to CY 2016 utilization (claims) data to total

payments when CY 2017 case-mix weights are applied to CY 2016 utilization data. The case-mix budget neutrality factor for CY 2018 would be 1.0159 as described in section III.B of this proposed rule.

Next, we would apply a reduction of 0.97 percent to the national, standardized 60-day payment rate for CY 2018 to account for nominal case-mix growth between CY 2012 and CY 2014. Lastly, we would update the proposed payment rates by the proposed CY 2018 home health payment update percentage of 1 percent as mandated by section 1895(b)(3)(B)(iii) of the Act. The proposed CY 2018 national, standardized 60-day episode payment rate is calculated in Table 9.

TABLE 9—PROPOSED CY 2018 60-DAY NATIONAL, STANDARDIZED 60-DAY EPISODE PAYMENT AMOUNT

CY 2017 national, standardized 60-day episode payment	Wage index budget neutrality factor	Case-mix weights budget neutrality factor	Nominal case-mix growth adjustment (1–0.0097)	Proposed CY 2018 HH payment update	Proposed CY 2018 national, standardized 60-day episode payment
\$2,989.97	× 1.0001	× 1.0159	× 0.9903	× 1.01	\$3,038.43

The proposed CY 2018 national, standardized 60-day episode payment rate for an HHA that does not submit the

required quality data is updated by the proposed CY 2018 home health payment update of 1 percent minus 2

percentage points and is shown in Table 10.

TABLE 10—PROPOSED CY 2018 NATIONAL, STANDARDIZED 60-DAY EPISODE PAYMENT AMOUNT FOR HHAS THAT DO NOT SUBMIT THE QUALITY DATA

CY 2017 national, standardized 60-day episode payment	Wage index budget neutrality factor	Case-mix weights budget neutrality factor	Nominal case-mix growth adjustment (1–0.0097)	Proposed CY 2018 HH payment update minus 2 percentage points	Proposed CY 2018 national, standardized 60-day episode payment
\$2,989.97	× 1.0001	× 1.0159	× 0.9903	× 0.99	\$2,978.26

c. Proposed CY 2018 National Per-Visit Rates

The national per-visit rates are used to pay LUPAs (episodes with four or fewer visits) and are also used to compute imputed costs in outlier calculations. The per-visit rates are paid by type of visit or HH discipline. The six HH disciplines are as follows:

- Home health aide (HH aide);
- Medical Social Services (MSS);
- Occupational therapy (OT);
- Physical therapy (PT);
- Skilled nursing (SN); and
- Speech-language pathology (SLP).

To calculate the proposed CY 2018 national per-visit rates, we start with the CY 2017 national per-visit rates. We then apply a wage index budget

neutrality factor to ensure budget neutrality for LUPA per-visit payments. We calculate the wage index budget neutrality factor by simulating total payments for LUPA episodes using the proposed CY 2018 wage index and comparing it to simulated total payments for LUPA episodes using the CY 2017 wage index. By dividing the total payments for LUPA episodes using the proposed CY 2018 wage index by the total payments for LUPA episodes using the CY 2017 wage index, we obtain a wage index budget neutrality factor of 1.0005. We would apply the wage index budget neutrality factor of 1.0005 in order to calculate the CY 2018 national per-visit rates.

The LUPA per-visit rates are not calculated using case-mix weights. Therefore, there is no case-mix weights budget neutrality factor needed to ensure budget neutrality for LUPA payments. Lastly, the per-visit rates for each discipline are updated by the proposed CY 2018 home health payment update percentage of 1 percent. The national per-visit rates are adjusted by the wage index based on the site of service of the beneficiary. The per-visit payments for LUPAs are separate from the LUPA add-on payment amount, which is paid for episodes that occur as the only episode or initial episode in a sequence of adjacent episodes. The proposed CY 2018 national per-visit rates are shown in Tables 11 and 12.

TABLE 11—PROPOSED CY 2018 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA

HH discipline type	CY 2017 per-visit payment	Wage index budget neutrality factor	Proposed CY 2018 HH payment update	Proposed CY 2018 per-visit payment
Home Health Aide	\$64.23	× 1.0005	× 1.01	\$64.90
Medical Social Services	227.36	× 1.0005	× 1.01	229.75
Occupational Therapy	156.11	× 1.0005	× 1.01	157.75
Physical Therapy	155.05	× 1.0005	× 1.01	156.68
Skilled Nursing	141.84	× 1.0005	× 1.01	143.33
Speech- Language Pathology	168.52	× 1.0005	× 1.01	170.29

The proposed CY 2018 per-visit payment rates for HHAs that do not submit the required quality data are

updated by the proposed CY 2018 HH payment update percentage of 1 percent

minus 2 percentage points and are shown in Table 12.

TABLE 12—PROPOSED CY 2018 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

HH discipline type	CY 2017 per-visit rates	Wage index budget neutrality factor	Proposed CY 2018 HH payment update minus 2 percentage points	Proposed CY 2018 per-visit rates
Home Health Aide	\$64.23	× 1.0005	× 0.99	\$63.62
Medical Social Services	227.36	× 1.0005	× 0.99	225.20
Occupational Therapy	156.11	× 1.0005	× 0.99	154.63
Physical Therapy	155.05	× 1.0005	× 0.99	153.58
Skilled Nursing	141.84	× 1.0005	× 0.99	140.49
Speech- Language Pathology	168.52	× 1.0005	× 0.99	166.92

d. Low-Utilization Payment Adjustment (LUPA) Add-On Factors

LUPA episodes that occur as the only episode or as an initial episode in a sequence of adjacent episodes are adjusted by applying an additional amount to the LUPA payment before adjusting for area wage differences. In the CY 2014 HH PPS final rule, we changed the methodology for calculating the LUPA add-on amount by finalizing the use of three LUPA add-on factors: 1.8451 for SN; 1.6700 for PT; and 1.6266 for SLP (78 FR 72306). We multiply the per-visit payment amount for the first SN, PT, or SLP visit in LUPA episodes that occur as the only episode or an initial episode in a sequence of adjacent episodes by the appropriate factor to determine the LUPA add-on payment amount. For example, in the case of HHAs that do

submit the required quality data, for LUPA episodes that occur as the only episode or an initial episode in a sequence of adjacent episodes, if the first skilled visit is SN, the payment for that visit would be \$264.46 (1.8451 multiplied by \$143.33), subject to area wage adjustment.

e. Proposed CY 2018 Non-Routine Medical Supply (NRS) Payment Rates

Payments for NRS are computed by multiplying the relative weight for a particular severity level by the NRS conversion factor. To determine the proposed CY 2018 NRS conversion factor, we update the CY 2017 NRS conversion factor (\$52.50) by the proposed CY 2018 home health payment update percentage of 1 percent. We do not apply a standardization factor as the NRS payment amount

calculated from the conversion factor is not wage or case-mix adjusted when the final claim payment amount is computed. The proposed NRS conversion factor for CY 2018 is shown in Table 13.

TABLE 13—PROPOSED CY 2018 NRS CONVERSION FACTOR FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA

CY 2017 NRS conversion factor	Proposed CY 2018 HH payment update	Proposed CY 2018 NRS conversion factor
\$52.50	× 1.01	\$53.03

Using the CY 2018 NRS conversion factor, the payment amounts for the six severity levels are shown in Table 14.

TABLE 14—PROPOSED CY 2018 NRS PAYMENT AMOUNTS FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA

Severity level	Points (scoring)	Relative weight	Proposed CY 2017 NRS payment amounts
1	0	0.2698	\$ 14.31
2	1 to 14	0.9742	51.66
3	15 to 27	2.6712	141.65
4	28 to 48	3.9686	210.45

TABLE 14—PROPOSED CY 2018 NRS PAYMENT AMOUNTS FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA—Continued

Severity level	Points (scoring)	Relative weight	Proposed CY 2017 NRS payment amounts
5	49 to 98	6.1198	324.53
6	99+	10.5254	558.16

For HHAs that do not submit the required quality data, we update the CY 2017 NRS conversion factor (\$52.50) by the proposed CY 2018 home health payment update percentage of 1 percent minus 2 percentage points. The proposed CY 2018 NRS conversion factor for HHAs that do not submit quality data is shown in Table 15.

TABLE 15—PROPOSED CY 2018 NRS CONVERSION FACTOR FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

CY 2017 NRS conversion factor	Proposed CY 2018 HH payment update percentage minus 2 percentage points	Proposed CY 2018 NRS conversion factor
\$52.50	× 0.99	\$51.98

The payment amounts for the various severity levels based on the updated conversion factor for HHAs that do not submit quality data are calculated in Table 16.

TABLE 16—PROPOSED CY 2018 NRS PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

Severity level	Points (scoring)	Relative weight	Proposed CY 2018 NRS payment amounts
1	0	0.2698	\$ 14.02
2	1 to 14	0.9742	50.64
3	15 to 27	2.6712	138.85
4	28 to 48	3.9686	206.29
5	49 to 98	6.1198	318.11
6	99+	10.5254	547.11

f. Rural Add-On

Section 421(a) of the MMA required, for HH services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes or visits ending on or after April 1, 2004, and before April 1, 2005, that the Secretary increase the payment amount that otherwise would have been made under section 1895 of the Act for the services by 5 percent.

Section 5201 of the DRA amended section 421(a) of the MMA. The amended section 421(a) of the MMA required, for HH services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act), on or after January 1, 2006, and before January 1, 2007, that the Secretary increase the payment amount otherwise made under section 1895 of the Act for those services by 5 percent.

Section 3131(c) of the Affordable Care Act amended section 421(a) of the MMA to provide an increase of 3 percent of the payment amount otherwise made under section 1895 of the Act for HH

services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes and visits ending on or after April 1, 2010, and before January 1, 2016.

Section 210 of the MACRA amended section 421(a) of the MMA to extend the rural add-on by providing an increase of 3 percent of the payment amount otherwise made under section 1895 of the Act for HH services provided in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes and visits ending before January 1, 2018. Therefore, for episodes and visits that end on or after January 1, 2018, a rural add-on payment will not apply.

D. Payments for High-Cost Outliers Under the HH PPS

1. Background

Section 1895(b)(5) of the Act allows for the provision of an addition or adjustment to the home health payment amount in the case of outliers because of unusual variations in the type or amount of medically necessary care.

Prior to the enactment of the Affordable Care Act, section 1895(b)(5) of the Act stipulated that projected total outlier payments could not exceed 5 percent of total projected or estimated HH payments in a given year. In the July 3, 2000 Medicare Program; Prospective Payment System for Home Health Agencies final rule (65 FR 41188 through 41190), we described the method for determining outlier payments. Under this system, outlier payments are made for episodes whose estimated costs exceed a threshold amount for each Home Health Resource Group (HHRG). The episode's estimated cost was established as the sum of the national wage-adjusted per-visit payment amounts delivered during the episode. The outlier threshold for each case-mix group or Partial Episode Payment (PEP) adjustment is defined as the 60-day episode payment or PEP adjustment for that group plus a fixed-dollar loss (FDL) amount. The outlier payment is defined to be a proportion of the wage-adjusted estimated cost

beyond the wage-adjusted threshold. The threshold amount is the sum of the wage and case-mix adjusted PPS episode amount and wage-adjusted FDL amount. The proportion of additional costs over the outlier threshold amount paid as outlier payments is referred to as the loss-sharing ratio.

In the CY 2010 HH PPS proposed rule (74 FR 40948, 40957), we stated that outlier payments increased as a percentage of total payments from 4.1 percent in CY 2005, to 5.0 percent in CY 2006, to 6.4 percent in CY 2007 and that this excessive growth in outlier payments was primarily the result of unusually high outlier payments in a few areas of the country. In that discussion, we noted that despite program integrity efforts associated with excessive outlier payments in targeted areas of the country, we discovered that outlier expenditures still exceeded the 5 percent target in CY 2007 and, in the absence of corrective measures, would continue to do so. Consequently, we assessed the appropriateness of taking action to curb outlier abuse. As described in the CY 2010 HH PPS final rule (74 FR 58080 through 58087), to mitigate possible billing vulnerabilities associated with excessive outlier payments and adhere to our statutory limit on outlier payments, we finalized an outlier policy that included a 10 percent agency-level cap on outlier payments. This cap was implemented in concert with a reduced FDL ratio of 0.67. These policies resulted in a projected target outlier pool of approximately 2.5 percent. (The previous outlier pool was 5 percent of total home health expenditures). For CY 2010, we first returned the 5 percent held for the previous target outlier pool to the national, standardized 60-day episode rates, the national per-visit rates, the LUPA add-on payment amount, and the NRS conversion factor. Then, we reduced the CY 2010 rates by 2.5 percent to account for the new outlier pool of 2.5 percent. This outlier policy was adopted for CY 2010 only.

As we noted in the CY 2011 HH PPS final rule (75 FR 70397 through 70399), section 3131(b)(1) of the Affordable Care Act amended section 1895(b)(3)(C) of the Act, and required the Secretary to reduce the HH PPS payment rates such that aggregate HH PPS payments were reduced by 5 percent. In addition, section 3131(b)(2) of the Affordable Care Act amended section 1895(b)(5) of the Act by redesignating the existing language as section 1895(b)(5)(A) of the Act, and revising the language to state that the total amount of the additional payments or payment adjustments for outlier episodes may not exceed 2.5

percent of the estimated total HH PPS payments for that year. Section 3131(b)(2)(C) of the Affordable Care Act also added section 1895(b)(5)(B) of the Act which capped outlier payments as a percent of total payments for each HHA at 10 percent.

As such, beginning in CY 2011, our HH PPS outlier policy is that we reduce payment rates by 5 percent and target up to 2.5 percent of total estimated HH PPS payments to be paid as outliers. To do so, we first returned the 2.5 percent held for the target CY 2010 outlier pool to the national, standardized 60-day episode rates, the national per visit rates, the LUPA add-on payment amount, and the NRS conversion factor for CY 2010. We then reduced the rates by 5 percent as required by section 1895(b)(3)(C) of the Act, as amended by section 3131(b)(1) of the Affordable Care Act. For CY 2011 and subsequent calendar years we target up to 2.5 percent of estimated total payments to be paid as outlier payments, and apply a 10 percent agency-level outlier cap.

In the CY 2017 HH PPS proposed and final rules (81 FR 43737 through 43742 and 81 FR 76702), we described our concerns regarding patterns observed in home health outlier episodes. Specifically, we noted that the methodology for calculating home health outlier payments may have created a financial incentive for providers to increase the number of visits during an episode of care to surpass the outlier threshold and simultaneously created a disincentive for providers to treat medically complex beneficiaries who require fewer but longer visits. Given these concerns, in the CY 2017 HH PPS final rule (81 FR 76702), we finalized changes to the methodology used to calculate outlier payments, using a cost-per-unit approach rather than a cost-per-visit approach. This change in methodology allows for more accurate payment for outlier episodes, accounting for both the number of visits during an episode of care and also the length of the visits provided. Using this approach, we now convert the national per-visit rates into per 15-minute unit rates. These per 15-minute unit rates are used to calculate the estimated cost of an episode to determine whether the claim will receive an outlier payment and the amount of payment for an episode of care. In conjunction with our finalized policy to change to a cost-per-unit approach to estimate episode costs and determine whether an outlier episode should receive outlier payments, in the CY 2017 HH PPS final rule we also finalized the implementation of a cap on the amount of time per day that would

be counted toward the estimation of an episode's costs for outlier calculation purposes (81 FR 76725). Specifically, we limit the amount of time per day (summed across the six disciplines of care) to 8 hours (32 units) per day when estimating the cost of an episode for outlier calculation purposes.

2. Fixed Dollar Loss (FDL) Ratio

For a given level of outlier payments, there is a trade-off between the values selected for the FDL ratio and the loss-sharing ratio. A high FDL ratio reduces the number of episodes that can receive outlier payments, but makes it possible to select a higher loss-sharing ratio, and therefore, increase outlier payments for qualifying outlier episodes.

Alternatively, a lower FDL ratio means that more episodes can qualify for outlier payments, but outlier payments per episode must then be lower.

The FDL ratio and the loss-sharing ratio must be selected so that the estimated total outlier payments do not exceed the 2.5 percent aggregate level (as required by section 1895(b)(5)(A) of the Act). Historically, we have used a value of 0.80 for the loss-sharing ratio which, we believe, preserves incentives for agencies to attempt to provide care efficiently for outlier cases. With a loss-sharing ratio of 0.80, Medicare pays 80 percent of the additional estimated costs above the outlier threshold amount.

Simulations based on CY 2015 claims data (as of June 30, 2016) completed for the CY 2017 HH PPS final rule showed that outlier payments were estimated to represent approximately 2.84 percent of total HH PPS payments in CY 2017, and as such, we raised the FDL ratio from 0.45 to 0.55. We stated that raising the FDL ratio to 0.55, while maintaining a loss-sharing ratio of 0.80, struck an effective balance of compensating for high-cost episodes while still meeting the statutory requirement to target up to, but no more than, 2.5 percent of total payments as outlier payments (81 FR 76726). The national, standardized 60-day episode payment amount is multiplied by the FDL ratio. That amount is wage-adjusted to derive the wage-adjusted FDL amount, which is added to the case-mix and wage-adjusted 60-day episode payment amount to determine the outlier threshold amount that costs have to exceed before Medicare would pay 80 percent of the additional estimated costs.

For this proposed rule, using preliminary CY 2016 claims data (as of March 17, 2017) and the proposed CY 2018 payment rates presented in section III.C of this proposed rule, we estimate that outlier payments would constitute

approximately 2.47 percent of total HH PPS payments in CY 2018 under the current outlier methodology. Given the statutory requirement to target up to, but no more than, 2.5 percent of total payments as outlier payments, we are not proposing a change to the FDL ratio for CY 2018 as we believe that maintaining an FDL ratio of 0.55 with a loss-sharing ratio of 0.80 is still appropriate given the percentage of outlier payments projected for CY 2018. Likewise, we are not proposing a change to the loss-sharing ratio (0.80) for the HH PPS to remain consistent with payment for high-cost outliers in other Medicare payment systems (for example, IRF PPS, IPPS, etc.). While we are not proposing to change the FDL ratio of 0.55 for CY 2018, we note that in the final rule, we will update our estimate of outlier payments as a percent of total HH PPS payments using the most current and complete year of HH PPS data (CY 2016 claims data as of June 30, 2017 or later). This may result in changes to the FDL ratio in the final rule.

E. Proposed Implementation of the Home Health Groupings Model (HHGM) for CY 2019

1. Overview, Data, and File Construction

Under the home health prospective payment system (HH PPS), Medicare pays for home health services provided during a 60-day episode of care. Episodes are case-mix adjusted based on the timing of the episode within a sequence of episodes, the patient's clinical status and functional status as determined using information from the Outcome and Assessment Information Set (OASIS), and the amount of therapy service provided during the episode. Therapy service use is measured by the number of therapy visits provided during the episode and can be categorized into nine visit level categories (or thresholds): 0–5; 6; 7–9; 10; 11–13; 14–15; 16–17; 18–19; and 20 or more visits. The combinations of episode timing, clinical and functional levels, and therapy service use categories result in 153 home health resource groups (HHRGs) into which home health episodes are categorized. Each HHRG is assigned a relative weight reflecting the average resource use of patients in that group compared with average resource use across all Medicare home health patients; this weight is then used to case mix adjust the episode's payment (with an additional adjustment for geographic variation in wages). Additional payment adjustments are made for very resource

intensive (outlier) episodes, episodes with very few visits, transfers to other HHAs or to hospitals with a return to home health during the episode, and the expected use of non-routine medical supplies (NRS).

As discussed in section II.D of this proposed rule, the Report to Congress, required by section 3131(d) of the Affordable Care Act, found that payment accuracy could be improved under the current payment system, particularly for patients with certain clinical characteristics.¹⁶ Findings from the report suggest that the current home health payment system may discourage HHAs from serving patients with clinically complex and/or poorly controlled chronic conditions who do not need therapy services, but require skilled nursing care. In addition, MedPAC believes that the Medicare home health benefit is ill-defined and the current reliance on therapy service thresholds for determining payment is counter to the goals of a prospective payment system. Under the current payment system, HHAs receive higher payments for providing more therapy visits, which may incentivize unnecessary utilization. MedPAC reiterated their recommendation in the March 2017 Report to Congress that CMS eliminate the use of the number of therapy visits as a payment factor in the home health PPS beginning in 2019.¹⁷

To better align payment with patient care needs and better ensure that clinically complex and ill beneficiaries have adequate access to home health care, we are proposing for CY 2019 case-mix methodology refinements through the implementation of the Home Health Groupings Model (HHGM). We propose to implement the HHGM for home health periods of care beginning on or after January 1, 2019. The implementation of the HHGM will require provider education and training, updating and revising relevant manuals, and changing claims processing systems. Implementation starting in CY 2019 would provide an opportunity for CMS, its contractors, and the agencies themselves to prepare. This patient-centered model groups periods of care

¹⁶ Report to Congress. *Medicare Home Health Study: An Investigation on Access to Care and Payment for Vulnerable Patient Populations*. Available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Downloads/HH-Report-to-Congress.pdf>.

¹⁷ Medicare Payment Advisory Commission (MedPAC). "Home Health Care Services." *Report to Congress: Medicare Payment Policy*. Washington, DC, March 2015. P. 233. Accessed on March 28, 2017 at http://www.medpac.gov/docs/default-source/reports/mar2015_entirereport_revised.pdf?sfvrsn=0.

in a manner consistent with how clinicians differentiate between patients and the primary reason for needing home health care. The HHGM uses 30-day periods rather than the 60-day episode used in the current payment system, eliminates the use of the number of therapy visits provided to determine payment, and relies more heavily on clinical characteristics and other patient information (for example, diagnosis, functional level, comorbid conditions, admission source) to place patients into clinically meaningful payment categories. In total, there are 144 different payment groups in the HHGM.

Costs during an episode/period of care are estimated based on the concept of resource use, which measures the costs associated with visits performed during a home health episode/period. For the current HH PPS case-mix weights, we use Wage Weighted Minutes of Care (WWMC), which uses data from the Bureau of Labor Statistics (BLS) reflecting the Home Health Care Service Industry. For the HHGM, we propose shifting to a Cost-Per-Minute plus Non-Routine Supplies (CPM + NRS) approach, which uses information from the Medicare Cost Report. The CPM + NRS approach incorporates a wider variety of costs (such as transportation) compared to the BLS estimates and the costs are available for individual HHA providers while the BLS costs are aggregated for the Home Health Care Service industry. The proposed methodology used to calculate the cost of an episode/period of care is discussed in detail in section III.E.2. of this proposed rule.

We propose using the 30-day periods rather than the 60-day episodes in the current payment system. Episodes have more visits, on average, during the first 30 days compared to the last 30 days.¹⁸ Costs are much higher earlier in the episode and lesser later on, therefore we believe that dividing a single 60-day episode into two 30-day periods more accurately apportions payments. Overall, we found that the average length of an episode of care was 47 days, but roughly a quarter of all 60 days episodes lasted 30 days or less. The proposed change from 60-day billing to 30-day billing under the HHGM is discussed in detail in section III.E.3. of this proposed rule.

¹⁸ Abt Associates. "Overview of the Home Health Groupings Model." *Medicare Home Health Prospective Payment System: Case-Mix Methodology Refinements*. Cambridge, MA, November 18, 2016. Available at <https://downloads.cms.gov/files/hhgm%20technical%20report%20120516%20sxf.pdf>.

Similar to the current payment system, 30-day periods under the HHGM would be classified as “early” or “late” depending on when they occur within a sequence of 30-day periods. Under the current HH PPS, the first two 60-day episodes of a sequence of adjacent 60-day episodes are considered early, while the third 60-day episode of that sequence and any subsequent episodes are considered late. Under the HHGM, the first 30-day period is classified as early. All subsequent 30-day periods in the sequence (second or later) are classified as late. We propose to adopt this episode timing classification for 30-day periods with the implementation of the HHGM. Similar to the current payment system, we propose that a 30-day period could not be considered early unless there was a gap of more than 60 days between the end of one period and the start of another. The comprehensive assessment would still be completed within 5 days of the start of care date and completed no less frequently than during the last 5 days of every 60 days beginning with the start of care date, as currently required by § 484.55, Condition of participation: Comprehensive assessment of patients. The proposed episode timing classification is discussed in detail in section III.E.4. of this proposed rule.

Under the HHGM, each period would be classified into one of two admission source categories—community or institutional—depending on what healthcare setting was utilized in the 14 days prior to home health. The 30-day period would be categorized as institutional if an acute or post-acute care stay occurred in the prior 14 days to the start of the 30-day period of care. The 30-day period would be categorized as community if there was no acute or post-acute care stay in the 14 days prior to the start of the 30-day period of care. We propose to adopt this categorization by admission source with the implementation of the HHGM. The proposed admission classification

source is discussed in detail in section III.E.5. of this proposed rule.

The HHGM would group 30-day periods into categories based on a variety of patient characteristics. Within the HHGM, one of the steps in case-mix adjusting the 30-day payment amount would include grouping periods into one of six clinical groups based on the principal diagnosis listed on the home health claim. We propose grouping periods into one of six clinical groups based on the principal diagnosis with the implementation of the HHGM. The principal diagnosis reported would provide information to describe the primary reason for which patients are receiving home health services under the Medicare home health benefit. The proposed six clinical groups, which are discussed in detail in section III.E.6. of this proposed rule, are as follows:

- Musculoskeletal Rehabilitation.
- Neuro/Stroke Rehabilitation.
- Wounds—Post-Op Wound

Aftercare and Skin/Non-Surgical Wound Care.

- Complex Nursing Interventions.
- Behavioral Health Care.
- Medication Management, Teaching and Assessment (MMTA).

Under the HHGM, each 30-day period would be placed into one of three functional levels. The level would indicate if, on average, given its responses on certain functional OASIS items, a 30-day period is predicted to have higher costs or lower costs. We propose classifying 30-day periods according to functional level. For each of the six clinical groups, we propose that periods would be further classified into one of three functional levels with roughly 33 percent of periods in each level. The creation of this functional level is very similar to how the functional level is created in the current payment system. The proposed functional levels and corresponding OASIS items are discussed in detail in section III.E.7. of this proposed rule.

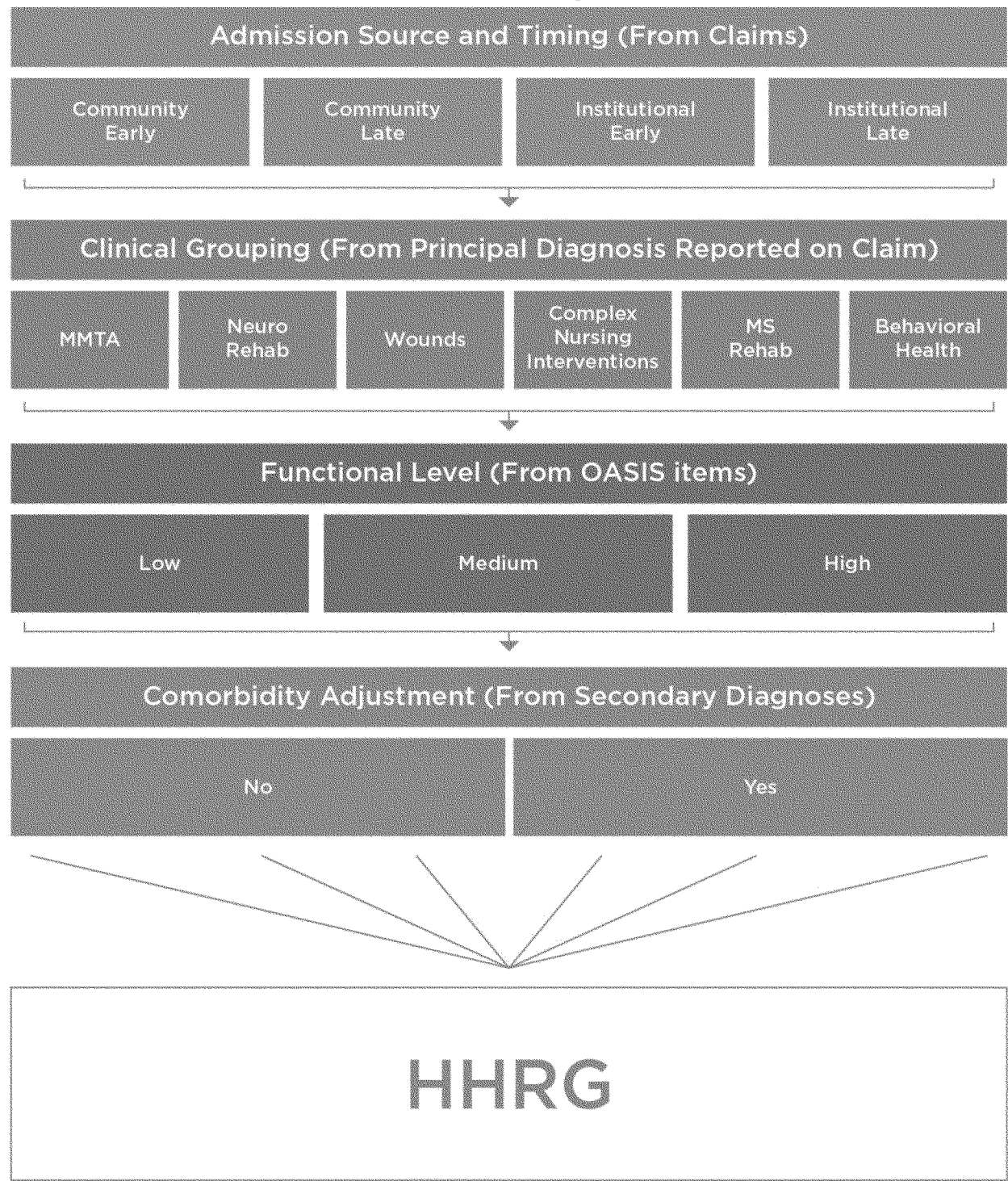
Exploratory analyses determined that comorbidities—that is, secondary diagnoses—provide additional information that can further explain

resource use differences across 30-day periods of care even after controlling for the primary diagnosis. Comorbidities are tied to poorer health outcomes, more complex medical need and management, and higher costs. The HHGM would include a comorbidity adjustment category based on the presence of secondary diagnoses. We propose that 30-day periods would receive a comorbidity adjustment if any diagnosis codes listed on the home health claim are included on a list of comorbidities that occurred in at least 0.1 percent of 30-day periods and associated with increased average resource use. The proposed comorbidity adjustment is discussed in detail in section III.E.8. of this proposed rule.

Currently, if an HHA provides four visits or less in an episode, they will be paid a standardized per visit payment instead of an episode payment for a 60-day episode of care. These payment adjustments are called Low-Utilization Payment Adjustments (LUPAs). While the HHGM would still include LUPAs, the approach to calculating the LUPA thresholds would need to change in the HHGM because of the switch to 30-day periods from 60-day episodes. Whereas there is a single LUPA threshold of 4 visits for all episodes under the current payment system, we propose the LUPA threshold would vary for a 30-day period under the HHGM depending on the HHGM payment group to which it was assigned. To create LUPA thresholds, 30-day periods (including those that were LUPAs in the current payment system) were grouped into the 144 different HHGM payment groups. For each payment group, we propose to use the 10th percentile value of visits to create a payment group specific LUPA threshold with a minimum threshold of at least 2 for each group. The proposed LUPA thresholds are discussed in more detail in section III.E.9. of this proposed rule.

Figure 5 represents how each 30-day period of care would be placed into one of 144 home health resource groups (HHRGs) under the proposed HHGM.

FIGURE 5: Structure of the Proposed HHGM



Under the Home Health Groupings Model, an episode is grouped into one (and only one) subcategory under each larger colored category. An episode's combination of subcategories groups the episode into one of 144 different payment groups.

While the proposed HHGM would reflect a change in the case-mix

adjustment methodology, the conditions for payment would remain the same for

Medicare home health services, meaning all requirements would still

need to be met in accordance with § 424.22. This includes physician certification that: (1) The individual is in need or needed intermittent skilled nursing care, or physical therapy or speech-language pathology services, and is confined to the home; (2) a plan of care has been established and will be periodically reviewed by a physician who is a doctor of medicine, osteopathy, or podiatric medicine; (3) the individual was under the care of a physician who is a doctor of medicine, osteopathy, or podiatric medicine; and, (4) a face-to-face patient encounter, which is related to the primary reason the patient requires home health services, occurred no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care and was performed by a physician or allowed non-physician practitioner. Likewise, under the HHGM, the Medicare beneficiary would retain all rights that currently exist under the current HH PPS, including those related to beneficiary liability for services or any reduction or termination of services. These would include the issuance of the Advanced Beneficiary Notice (ABN) and the Home Health Change of Care Notice (HHCCN), when appropriate. Medicare home health agencies are required to issue an ABN when a HHA believes Medicare will not pay for some or all of the patient's Medicare home health care. In these circumstances, if the beneficiary chooses to receive the items/services in question and Medicare does not cover the home health care, HHAs may use the ABN to shift liability for the non-covered home health care to the beneficiary. The HHCCN is a written notice that the HHA provides a beneficiary when his/her home health plan of care is changing because the home health agency makes a business decision to reduce or stop providing the patient some or all of the home health services or supplies OR the beneficiary's physician changed orders which may reduce or stop certain Medicare covered home health services or supplies.

To create the HHGM proposed model and related analyses, a data file based on home health episodes of care as reported in Medicare home health claims was utilized. The claims data provide episode-level data (for example, episode From and Through Dates, total number of visits, HHRG, diagnoses), as well as visit-level data (visit date, visit length in 15-minute units, discipline of the staff, etc.). The claims also provide data on whether NRS was provided during the episode and total charges for NRS.

The core file for most of the analyses for this proposed rule includes 100

percent of home health episode claims with Through Dates in Calendar Year (CY) 2016, processed by March 17, 2017, accessed via the Chronic Conditions Data Warehouse (CCW). Original or adjustment claims processed after March 17, 2017, would not be reflected in the core file. The claims-based file was supplemented with additional variables that were obtained from the CCW, such as information regarding other Part A and Part B utilization.

The data were cleaned by processing any remaining adjustments and by excluding duplicates and claims that were Requests for Anticipated Payment (RAP). In addition, visit-level variables needed for the analysis were extracted from the revenue center trailers (that is, the line items that describe the visits) and downloaded as a separate visit-level file, with selected episode-level variables merged onto the records for visits during those episodes. To account for potential data entry errors, the visit-level variables for visit length were top-censored at eight hours.¹⁹

A set of data cleaning exclusions were applied to the episode-level file, which resulted in the exclusion of the following:

- Episodes with no covered visits.
- Episodes with any missing units or visit data.
- Episodes with zero payments.
- Episodes with no charges.
- Non-LUPA episodes missing an HHRG.

The analysis file also includes data on patient characteristics obtained from the OASIS assessments conducted by HHA staff at the start of each episode. The assessment data are electronically submitted by home health agencies (HHAs) to a central CMS repository. In constructing the core data file, 100 percent of the OASIS assessments submitted October 2015, through December 2016 from the CMS repository were uploaded by CMS to the CCW. A CCW-derived linking key (Bene_ID) was used to match the OASIS data with CY 2016 episodes of care. Episodes that could not be linked with an OASIS assessment were excluded from the analysis file, as they included insufficient patient-level data to create the HHGM.

To construct measures of resource use, a variety of data sources were used (see section III.E.2 of this proposed rule for the proposed methodology used to calculate the cost of care under the HHGM). First, BLS data on average wages and fringe benefits were used to

produce one version of the wage-weighted cost per minute for each home health discipline. The wage data are for North American Industry Classification System (NAICS) 621600—Home Health Care Services. The wage data are broken down by the following occupations:

TABLE 17—BLS STANDARD OCCUPATION CLASSIFICATION (SOC) CODES FOR HOME HEALTH PROVIDERS

Standard Occupation Code (SOC) No.	Occupation title
29-1141	Registered Nurses.
29-2061	Licensed Practical and Licensed Vocational Nurses.
29-1123	Physical Therapists.
31-2021	Physical Therapist Assistants.
31-2022	Physical Therapist Aides.
29-1122	Occupational Therapists.
31-2011	Occupational Therapist Assistants.
31-2012	Occupational Therapist Aides.
29-1127	Speech-Language Pathologists.
21-1022	Medical and Public Health Social Workers.
21-1023	Mental Health and Substance Abuse Social Workers.
31-1011	Home Health Aides.

For visits where the service provided—as indicated by the Healthcare Common Procedure Coding System (HCPCS) code—can be provided by only a single standard occupation classification code; for example, establishment or review of a plan of care by a registered nurse (RN; HCPCS = G0162), the wage (and fringe) rate for that standard occupation classification is used to calculate the cost of the minutes for the visit. For visits where the service provided can potentially be provided by different standard occupation classification, such as observation and assessment by an RN or a Licensed Practical Nurse (LPN; HCPCS = G0163), a blended rate is applied, with the rate for each standard occupation classification code weighted by the total home health employment for that standard occupation classification code. The employment data are available from the same BLS table as the wage data.

Home Health Agency Medicare Cost Report (MCR) data were also used to construct a measure of resource use after trimming out HHAs whose costs were outliers. These data are used to provide a representation of the average costs of visits provided by HHAs in the six Medicare home health disciplines: Skilled nursing; physical therapy; occupational therapy; speech-language pathology; medical social services; and home health aide services. Cost report

¹⁹ Less than 0.1 percent of all visits were recorded as having greater than 8 hours of service.

data are publicly available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/>.

The 2016 analytic file included 6,293,442 episodes. Of these, 469,346 (7.5 percent) were excluded because they could not be linked to OASIS assessments or because of the reasons listed above. This yielded an analysis file including 5,824,096 episodes. Those episodes are 60-day episodes under the current payment system, but for the HHGM those 60-day episodes were converted into two 30-day periods. This yielded a final HHGM analytic file that included 10,231,507, 30-day periods. Certain 30-day periods were excluded for the following reasons:

- Periods missing a diagnosis code or where the diagnosis code did not link to a clinical group to case-mix adjust the period's payment (after exclusions, $n = 10,177,949$).

- Inability to merge to certain OASIS items to create the episode's functional level that is used for risk adjustment. For all the periods in the analytic file, there was a look-back through CY 2015 for a Start of Care or Resumption of Care assessment that preceded the period being analyzed and was in the same sequence of periods. If such an assessment was found, it was used to impute responses for OASIS items that were not included in the follow-up assessment. Periods which did not link to a Start of Care or Resumption of Care assessment were dropped (after exclusions, $n = 9,477,856$).

- No nursing visits or therapy visits (after exclusions, $n = 9,290,340$).

- LUPAs were excluded from the analysis. Periods that are identified as LUPAs in the current payment system are excluded in the creation of the functional score. Following the creation of the score (and the corresponding levels), case-mix group specific LUPA thresholds were created and episodes/periods were excluded that were below the new LUPA threshold when computing the case-mix weights.²⁰ Therefore, the final analytic sample included 8,642,107 30-day periods that were used for the analyses in the HHGM.

As noted in section II.D of this proposed rule, the analyses and the

²⁰ The case-mix group specific LUPA thresholds were determined using episodes that were considered LUPAs under the current payment system.

ultimate development of Home Health Groupings Model (HHGM) have been shared with both internal and external stakeholders via technical expert panels, clinical workgroups, special open door forums, and in the CY 2017 HH PPS final rule (81 FR 76702). Technical expert panel and clinical workgroup webinars on the technical report were held in December 2016 and a detailed technical report was posted on the CMS home health agency Web page in December, providing opportunity for stakeholder feedback.²¹ We also held a National Provider call in January 2017, to further solicit feedback from the public.²²

2. Methodology Used To Calculate the Cost of Care

To construct the case-mix weights for the HHGM proposal, the costs of providing care needed to be determined. A Wage-Weighted Minutes of Care (WWMC) approach is used in the current payment system based on data from the BLS. However, we are proposing to adopt a Cost-per-Minute plus Non-Routine Supplies (CPM + NRS) approach, which uses information from Medicare Cost Reports (MCR). We used the following data sources and methodology for calculating these measures of resource use:

- *BLS Wage Estimates*: For the WWMC method of calculating home health resource use, wage and fringe data was obtained from the BLS by industry code from the NAICS and occupation code from the Standard Operation Classification. These data provide nationwide average wage rates and the average value of fringe benefits per hour of work for specific occupations.

- *Home Health Medicare Cost Report Data*: All Medicare-certified HHAs must report their own costs through publicly-available home health cost reports

²¹ Abt Associates. "Overview of the Home Health Groupings Model." *Medicare Home Health Prospective Payment System: Case-Mix Methodology Refinements*. Cambridge, MA, November 18, 2016. Available at <https://downloads.cms.gov/files/hhgm%20technical%20report%20120516%20sxf.pdf>.

²² Centers for Medicare & Medicaid Services (CMS). "Certifying Patients for the Medicare Home Health Benefit." MLN Connects™ National Provider Call. Baltimore, MD, December 16, 2016. Slides, examples, audio recording and transcript available at <https://www.cms.gov/Outreach-and-Education/Outreach/NPC/National-Provider-Calls-and-Events-Items/2017-01-18-Home-Health.html?DLPage=2&DLEntries=10&DLSort=0&DLSortDir=descending>.

maintained by the Healthcare Cost Report Information System (HCRIS). Freestanding HHAs report HHA-specific cost reports while HHAs that are hospital-based report on the HHA component of the hospital cost reports. These cost reports enable estimation of the cost per visit by provider and the estimated NRS cost to charge ratios. To obtain a more robust estimate of cost, a trimming process was applied to remove cost reports with missing or questionable data and extreme values.²³

- *Home Health Claims Data*: Medicare home health claims data are used in both the WWMC and CPM+NRS methods to obtain minutes of care by discipline of care.

- *Wage-Weighted Minutes of Care (WWMC) Approach*: Used in the current payment system, this approach determines resource use for each episode by multiplying utilization (in terms of the number of minutes of direct patient care provided by each discipline) by the corresponding opportunity cost of that care (represented by wage and fringe benefit rates from the BLS).²⁴ Table 18 shows the occupational titles and corresponding mean hourly wage rates from the BLS. The employer cost per hour worked shown in the fifth column is calculated by adding together the mean hourly wage rates and the fringe benefit rates from the BLS (generally around 37 percent of wages). For home health disciplines that include multiple occupations (such as skilled nursing), the opportunity cost is generated by weighting the employer cost by the proportions of the labor mix.²⁵ Otherwise, the opportunity cost is the same as the employer cost per hour.

²³ The trimming methodology is described in the report "Analyses in Support of Rebasing & Updating Medicare Home Health Payment Rates" (Morefield, Christian, and Goldberg 2013). See <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Downloads/Analyses-in-Support-of-Rebasing-and-Updating-the-Medicare-Home-Health-Payment-Rates-Technical-Report.pdf>.

²⁴ Opportunity costs represent the foregone resources from providing each minute of care versus using the resources for another purpose (the next best alternative). Generally, opportunity costs represent more than the monetary costs, but in these analyses, they are proxied using hourly wage rates.

²⁵ Labor mix represents the percentage of employees with a particular occupational title (as obtained from the BLS) within a home health discipline.

TABLE 18—OCCUPATIONAL EMPLOYMENT AND WAGES PROVIDED BY THE FEDERAL BUREAU OF LABOR STATISTICS

Occupation title	National employment counts	Mean hourly wage	Estimate of benefits as a % of wages	Estimated employer cost per hour worked	Labor mix	Home health discipline	Opportunity cost
Registered Nurses.	173,590	\$32.94	43.76	\$47.36	0.68	Skilled Nursing	\$42.21
Licensed Practical and Licensed Vocational Nurses.	82,860	21.86	43.76	31.43	0.32		
Physical Therapists.	25,700	46.42	39.91	64.95	0.76	Physical Therapy	59.18
Physical Therapist Assistants.	7,460	30.81	35.75	41.83	0.22		
Physical Therapist Aides.	500	15.85	35.75	21.52	0.01		
Occupational Therapists.	10,780	44.17	39.91	61.80	0.82	Occupational Therapy	58.46
Occupational Therapist Assistants.	2,220	32.03	35.75	43.48	0.17		
Occupational Therapist Aides.	110	25.20	35.75	34.21	0.01		
Speech-Language Pathologists.	5,340	46.83	39.91	65.52		Speech Therapy	65.52
Medical and Public Health Social Workers.	17,270	28.16	39.91	39.40	0.97	Medical Social Service	39.35
Mental Health and Substance Abuse Social Workers.	450	26.87	39.91	37.59	0.03		
Home Health Aides.	385,440	10.93	35.75	14.84		Home Health Aide	14.84

Source: May 2015 National Industry-Specific Occupational Employment and Wage Estimates NAICS 621600—Home Health Care Services.

For each home health period of care, the number of minutes of care provided (obtained from the home health claims) is weighted by the corresponding opportunity cost for each discipline

providing the minutes. The resulting wage-weighted minutes of care are summed for the 30-day period to obtain total costs. Table 19 shows these costs overall for 30-day periods in CY 2016 (n

= 8,642,107). On average, total period costs were \$374.52. The distribution ranged from a 5th percentile value of \$73.87 to a 95th percentile value of \$912.10.

TABLE 19—DISTRIBUTION OF AVERAGE RESOURCE USE USING WWMC APPROACH

[30 day periods]

Statistics	Mean	N	5th Percentile	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile	95th Percentile
Average Resource Use (WWMC)	\$374.52	8,642,107	\$73.87	\$94.97	\$158.29	\$303.19	\$517.063	\$749.22	\$912.10

In the current HH PPS, all episodes without a LUPA payment receive payment for NRS, regardless of whether or not the HHA provided NRS during that episode. NRS payment amounts are determined through a payment model separately from the one used to construct the episode's case-mix weight.

The current payment system determines NRS payment using the presence of clinical factors associated with NRS provision from the OASIS. Two-thirds of episodes do not include provision of NRS, yet those episodes still receive an NRS payment.

We are proposing to calculate resource use under the HHGM using a Cost-per-Minute plus Non-Routine Supplies (CPM + NRS) approach. It determines resource use using information from Medicare cost reports. Under the proposed HHGM, we would group episodes into their case-mix

groups taking into account admission source, timing, clinical group, functional level, and comorbidity adjustment. From there, the average resource use for each case-mix group dictates the group's case-mix weight. Resource use is the estimated cost of visits recorded on the home health claim plus the cost of NRS recorded on the claims. The cost of NRS is generated by taking NRS charges on claims and converting them to costs using a NRS cost to charge ratio that is specific to each HHA. When NRS is factored into the average resource use, NRS costs are reflected in the average resource use that drives the case-mix weights. CMS would return \$53.03 to the base rate (that is, the NRS conversion factor). If there is a high amount of NRS cost for all episodes in a particular group (holding all else equal), the resource use will be higher relative to the average and the case-mix weight will correspondingly be higher. Similar to the current system, NRS would still be paid prospectively under the HHGM, but the HHGM eliminates the separate case-mix adjustment model for NRS. Incorporating the NRS cost into the measure of overall resource use (that is, the dependent variable of the payment model) requires adjusting the NRS charges submitted on claims based on the NRS cost-to-charge ratio from cost report data.

The following steps would be used to generate the measure of resource use under this CPM + NRS approach:

(1) From the cost reports, obtain total costs for each of the six home health disciplines for each HHA.

(2) From the cost reports, obtain the number of visits by each of the six home health disciplines for each HHA.

(3) Calculate discipline-specific cost per visit values by dividing total costs [1] by number of visits [2] for each discipline for each HHA. For HHAs that did not have a cost report available (or a cost report that was trimmed from the sample), imputed values were used as follows:

- A state-level mean was used if the HHA was not hospital-based. The state-level mean was computed using all non-hospital based HHAs in each state.

- An urban nationwide mean was used for all hospital-based HHAs located in a Core-based Statistical Area (CBSA). The urban nation-wide mean was computed using all hospital-based HHAs located in any CBSA.

- A rural nationwide mean was used for all hospital-based HHAs not in a CBSA. The rural nation-wide mean was computed using all hospital-based HHAs not in a CBSA.

(4) From the home health claims data, obtain the average number of minutes of care provided by each discipline across all episodes for a HHA.

(5) From the home health claims data, obtain the average number of visits provided by each discipline across all episodes for each HHA.

(6) Calculate a ratio of average visits to average minutes by discipline by dividing average visits provided [5] by average minutes of care [4] by discipline for each HHA.

(7) Calculate costs per minute by multiplying the HHA's cost per visit [3]

by the ratio of average visits to average minutes [6] by discipline for each HHA.

(8) Obtain 30-day period costs by multiplying costs per minute [7] by the total number of minutes of care provided during a 30-day period by discipline. Then, sum these costs across the disciplines for each period.

This approach accounts for variation in the length of a visit by discipline. NRS costs are added to the resource use calculated in [8] in the following way:

(9) From the cost reports, determine the NRS cost-to-charge ratio for each HHA. The NRS ratio is trimmed if the value falls in the top or bottom 1 percent of the distribution across all HHAs from the trimmed sample. Imputation for missing or trimmed values is done in the same manner as it was done for cost per visit (see [3] above).

(10) From the home health claims data, obtain NRS charges for each period.

(11) Obtain NRS costs for each period by multiplying charges from the home health claims data [10] by the cost-to-charge ratio from the cost reports [9] for each HHA.

Resource use is then obtained by:

(12) Summing costs from [8] with NRS costs from [11] for each 30-day period.

Table 20 shows these costs overall for 30-day periods in CY 2015 (n = 8,642,107). On average, total 30-day period costs are \$1,585.48. The distribution ranges from a 5th percentile value of \$300.03 to a 95th percentile value of \$3,908.93.

TABLE 20—DISTRIBUTION OF AVERAGE RESOURCE USE USING CPM + NRS APPROACH
[30 day periods]

Statistics	Mean	N	5th Percentile	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile	95th Percentile
Average Resource Use (CPM + NRS)	\$1,585.48	8,642,107	\$300.03	\$396.82	\$671.96	\$1262.65	\$2,119.49	\$3,135.38	\$3,908.93

The distributions and magnitude of the estimates of costs for the two methods are very different. The differences arise because the CPM + NRS method incorporates HHA-specific costs that represent the total costs incurred during a 30-day period (including overhead costs), while the WWMC method provides an estimate of only the labor costs (wage + fringe) related to direct patient care from patient visits that are incurred during a 30-day period. Those costs are not HHA-specific and do not account for any non-labor costs (such as transportation costs)

or the non-direct patient care labor costs (such as, administration and general labor costs). Because the costs estimated using the two approaches are measuring different items, they cannot be directly compared. However, if the true cost of a 30-day period is correlated with the labor that is provided during visits, the two approaches should be highly correlated. The correlation coefficient between the two approaches to calculating resource use is equal to 0.8016 (n = 8,642,107). Therefore, the relationship in relative costs is similar between the two methods.

Using cost report data to develop case-mix weights more evenly weights skilled nursing services and therapy services than the BLS data. Table 21 shows the ratios between the estimated costs per hour for each of the home health disciplines compared with skilled nursing resulting from the CPM + NRS versus WWMC methods. Under the CPM+NRS methodology, the ratio for physical therapy costs per hour to skilled nursing is 1.14 compared with 1.40 using the WWMC method.

TABLE 21—RELATIVE VALUES IN COSTS PER HOUR BY DISCIPLINE
[Skilled nursing is base]

Estimated cost per hour	Skilled nursing	Physical therapy	Occupational therapy	Speech therapy	Medical social service	Home health aide
CPM+NRS	1.00	1.14	1.16	1.24	1.36	0.41
WWMC	1.00	1.40	1.39	1.50	0.95	0.36

We believe that using cost report data to calculate the cost of home health care better aligns the case-mix weights with the total relative cost for treating various patients. In addition, using cost report data allows us to incorporate NRS into the case-mix system, rather than maintaining a separate payment system. Therefore, we are proposing to calculate the cost of a 30-day period of home health care under the HHGM using the cost per minute plus non-routine supplies (CPM+NRS) approach outlined above. We invite comments on the proposed methodology for calculating the cost of a 30-day period of care under the HHGM.

3. Change From 60-Day Billing to 30-Day Billing Under the HHGM

a. 30-Day Unit of Payment

Currently, HHAs are paid for each 60-day episode of home health care provided. We are proposing 30-day periods of payment for the HHGM. Through examination of the resources used within a 60-day episode of care, we identified differences in resources used between the first 30-day period within a 60-day episode and the second 30-day period within a 60-day episode. Episodes have more visits, on average, during the first 30 days compared to the last 30 days (see Tables 22 and 23). Costs are much higher earlier in the episode and lesser later on, therefore, dividing a single 60-day episode into two 30-day periods more accurately apportions payments. This difference in resource use between the first and second 30-day period within a 60-day episode is one of the main reasons we are proposing 30-day periods of payment for the HHGM. Another reason for proposing to change the unit of payment from 60-days to 30-days is the removal of the therapy visit thresholds from the case-mix adjustment methodology under the HHGM (the current system accounts for therapy visit variation through the use of these thresholds). Without thresholds being used to account for resource use variation, a shorter period of care is

needed to reduce the variation and improve the accuracy of the case-mix weights generated under the HHGM. The HHGM's goodness of fit statistics (for example, R-squared) improve due to reduced resource use variation when a shorter, more constrained time period is examined. Therefore, the case-mix weights and proposed move to a 30-day period under the HHGM better approximate relative resource use. Furthermore, by switching to a 30-day period, the billing cycle for Medicare home health services would be the same as for other Medicare health care settings, such as hospices and SNFs, which currently bill on a monthly basis.

Using two segments of the current 60-day episodes, 30-day periods were constructed as follows for the development of the HHGM:

- A 30-day period comprising days 1–30 of a current 60-day episode where “day 1” is the current 60-day episode's From Date.
- A second period comprising days 31 and above of a current 60-day episode. This period would be 30-days in length if the current episode was 60-days (from the From Date of the episode to the Through Date of the episode) and some lesser length if the current episode were fewer than 60-days.

A typical 60-day episode was broken down into two portions: A first 30-day period; and a second 30-day period consisting of the remaining days. For example, if the current episode was 58 days, then the first period was 30-days, and the second period was comprised of the remaining 28 days. Resource utilization was calculated for each 30-day period based on the discipline visits that occur within each respective 30-day time span. The OASIS information that is applied to the two 30-day periods (for example, OASIS information) is established by the same OASIS that is linked to the current 60-day episode.

Table 22 shows the average number of visits by discipline and resource use estimates during 15-day periods in a 60-day episode, and shows that visit patterns differ over the course of a 60-day episode. Across all labor categories

there is a decline in visits as the episode proceeds; in total there are 6.8 visits on average in days 1–15 and 2.6 visits on average in days 46–60 which is a 61.8 percent decline from the first 15 days of care in a 60-day episode to the last 15 days of care in a 60-day episode.

Table 23 shows the average number of visits and resource use estimates by discipline during 15-day periods in a 60-day episode, but for only those episodes that are first in a sequence of episodes and last a full 60-days. A sequence of episodes contains episodes where no more than 60-days elapse from the end of one episode to the start of the next. Therefore, first episodes are those where the beneficiary has not had home health in the 60-days prior to the start of the first episode. Even among this subset of episodes, there is a decline in average visits by quarter as the episode proceeds.

These results show that there is variation in average resource use across 60-day episodes. By moving to two 30-day periods within a 60-day episode (or a single 30-day period if the 60-day episode contains 30 or fewer days), the HH PPS case mix weights better align with the resource use patterns across the current 60-day episode. Though the analyses are based on two 30-day periods in a 60-day episode, we are not proposing a change in the requirements for completing the comprehensive assessment. Under the HHGM, the comprehensive assessment would still be required, as outlined in § 484.55 roughly every 60-days as is required under the current HH PPS. While we examined resource use in 15-day periods in a 60-day episode of care, as outlined in Tables 22 and 23, in order to strike an appropriate balance between increasing payment accuracy and being cognizant of increasing burden for the home health industry, we are not proposing to adjust payments every 15 days. We expect that billing on a 30-day basis should not be completely unfamiliar to HHAs as HHAs billed as such prior to the implementation of the HH PPS.

TABLE 22—AVERAGE VISITS PER 15 DAYS DURING A 60-DAY EPISODE

	Days 1–15	Days 16–30	Days 31–45	Days 46–60
Average Daily Resource Use	\$261.97	\$162.44	\$107.49	\$88.67
Average Skilled Nursing Visits	3.3	2.1	1.6	1.4
Average PT Visits	2.2	1.7	1.0	0.6
Average OT Visits	0.6	0.5	0.3	0.2
Average SLP Visits	0.1	0.1	0.1	0.0
Average Aide Visits	0.5	0.5	0.4	0.3
Average MSS Visits	0.1	0.0	0.0	0.0
Average Total Visits	6.8	4.9	3.3	2.6

TABLE 23—AVERAGE VISITS PER 15 DAYS DURING A 60-DAY EPISODE

[Only First Episodes in a Sequence of Episodes That Last a Full 60-Days]

	Days 1–15	Days 16–30	Days 31–45	Days 46–60
Average Daily Resource Use	\$326.78	\$217.75	\$174.82	\$167.69
Average Skilled Nursing Visits	3.9	2.5	2.2	2.3
Average PT Visits	2.6	2.4	1.7	1.4
Average OT Visits	0.8	0.8	0.5	0.4
Average SLP Visits	0.1	0.2	0.1	0.1
Average Aide Visits	0.5	0.5	0.5	0.4
Average MSS Visits	0.1	0.1	0.0	0.0
Average Total Visits	8.1	6.4	5.1	4.6

Overall, approximately 25 percent of episodes are 30 days or less in length, and therefore, would produce no second 30-day period under the HHGM. These episodes (with 30 days or fewer) would convert to only one 30-day period each; any 60-day episode that is 31 days or more would produce two 30-day periods: A first period comprising 30 days in length and then a second period

with the remaining days in the 60-day episode.

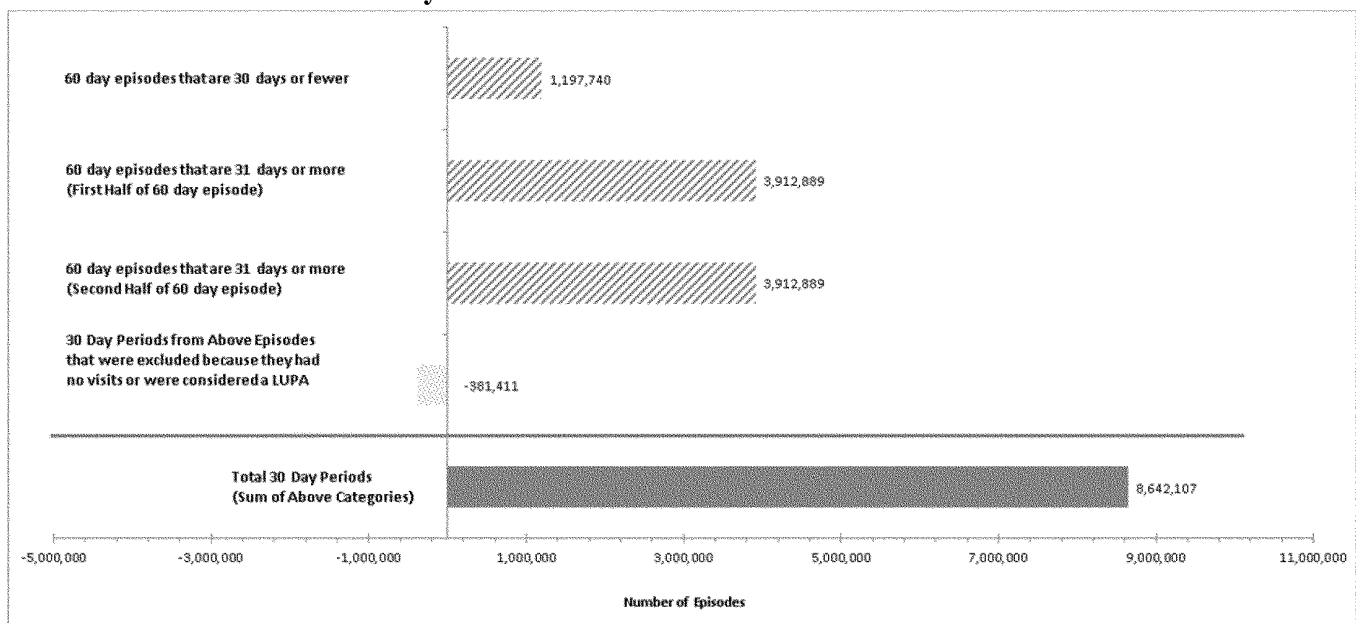
Overall, after conversion from the 5,110,629 60-day episodes, there were 8,642,107 30-day periods:

- There were 1,197,740 30-day periods that could potentially be one-to-one conversions from 60-day episodes that were 30-days or fewer in length.
- Additionally, there were 3,912,889 60-day episodes that were between 31

and 60-days in length in which two 30-day periods could be produced. That is, those 60-day episodes could produce up to 7,825,778 30-day periods.

- However, from the above episodes (which were used to create the 30-day periods), there were 381,411 periods that had no visits included or were considered a LUPA under the HHGM and therefore were excluded. This is shown in Table 24.

TABLE 24: Total Numbers of 60-day Episodes and 30-day Simulated Home Health Periods



Tables 25 and 26 show the frequency of episode length in days and estimates of resource use among the original, 60-day episodes and the corresponding distribution of episode length and

resource use estimates among the simulated 30-day periods. Again, these results show differences by the length of care. By shortening the unit of time that CMS pays for within the HH PPS (from

60-day episodes to 30-day periods), payment would more accurately relate to the variation in costs seen across episodes and periods of care.

TABLE 25—FREQUENCY OF LENGTH OF 60-DAY EPISODES AND AVERAGE RESOURCE USE FOR EPISODES OF A CERTAIN LENGTH

Length of episode in days	Number of episodes	Percent of episodes	Average resource use	Standard deviation of resource use	25th Percentile of resource use	Median resource use	75th Percentile of resource use
1	189	0.0	\$390.10	\$200.87	\$348.85	\$249.99	\$495.03
2	1,204	0.0	542.52	348.55	453.72	318.34	673.97
3	3,796	0.1	673.54	418.19	596.78	403.37	846.78
4	6,051	0.1	751.09	474.35	667.26	447.37	940.19
5	9,385	0.2	829.89	521.12	730.17	506.40	1,021.84
6	11,793	0.2	873.31	505.81	785.61	542.35	1,083.79
7	16,587	0.3	941.17	560.28	838.68	588.23	1,152.63
8	19,887	0.4	972.38	556.43	875.29	613.68	1,200.88
9	21,026	0.4	1,024.75	592.64	920.13	641.04	1,272.40
10	25,724	0.5	1,078.33	623.90	965.80	671.36	1,345.45
11	29,757	0.6	1,130.59	645.67	1,021.82	708.30	1,418.14
12	34,725	0.7	1,210.00	661.38	1,094.30	769.13	1,515.79
13	40,923	0.8	1,264.30	704.44	1,138.39	791.18	1,585.99
14	49,796	1.0	1,328.34	737.07	1,194.49	829.00	1,667.27
15	55,035	1.1	1,348.52	744.31	1,210.83	840.75	1,697.71
16	47,921	0.9	1,386.45	780.24	1,245.80	850.81	1,754.75
17	48,442	0.9	1,417.42	818.41	1,265.56	865.41	1,796.48
18	48,802	1.0	1,467.76	851.49	1,311.49	883.41	1,864.69
19	48,998	1.0	1,538.06	887.62	1,377.47	926.88	1,955.85
20	53,699	1.1	1,583.97	897.61	1,427.87	954.98	2,014.18
21	59,071	1.2	1,649.78	939.64	1,482.19	995.89	2,097.03
22	66,055	1.3	1,678.50	958.48	1,501.48	1,012.61	2,129.05
23	58,291	1.1	1,743.90	995.17	1,565.59	1,047.09	2,225.60
24	59,211	1.2	1,797.28	1,026.42	1,605.71	1,085.07	2,292.14
25	58,481	1.1	1,847.21	1,059.00	1,656.07	1,103.81	2,363.45
26	58,245	1.1	1,919.71	1,098.44	1,734.72	1,145.08	2,456.08
27	63,077	1.2	1,976.10	1,115.08	1,799.37	1,188.51	2,534.66
28	67,228	1.3	2,038.34	1,156.00	1,845.61	1,229.39	2,608.78
29	73,202	1.4	2,056.06	1,176.25	1,850.93	1,227.68	2,630.45
30	61,139	1.2	2,131.43	1,219.42	1,925.44	1,266.69	2,748.63
31	54,481	1.1	2,054.35	1,239.89	1,844.53	1,175.90	2,664.68
32	48,964	1.0	2,106.57	1,320.10	1,876.72	1,183.96	2,745.18
33	45,330	0.9	2,162.62	1,347.74	1,940.78	1,206.50	2,828.61
34	47,568	0.9	2,249.85	1,433.54	2,011.03	1,250.25	2,928.78
35	50,567	1.0	2,323.60	1,436.69	2,094.77	1,331.92	3,004.86
36	54,810	1.1	2,355.59	1,436.60	2,133.82	1,372.34	3,017.30
37	44,844	0.9	2,429.51	1,534.67	2,185.85	1,389.64	3,114.63
38	43,262	0.8	2,474.67	1,561.76	2,208.94	1,423.02	3,166.09
39	40,322	0.8	2,521.79	1,611.74	2,258.31	1,429.43	3,244.51
40	39,193	0.8	2,611.98	1,669.37	2,348.75	1,487.83	3,344.28
41	42,316	0.8	2,676.84	1,652.00	2,433.86	1,570.54	3,392.77
42	43,428	0.8	2,717.91	1,713.02	2,433.05	1,570.70	3,486.36
43	44,866	0.9	2,723.30	1,692.49	2,429.86	1,594.39	3,475.35
44	36,714	0.7	2,784.62	1,751.30	2,489.70	1,608.51	3,560.94
45	34,973	0.7	2,825.00	1,800.40	2,498.55	1,617.88	3,621.28
46	32,604	0.6	2,843.98	1,881.88	2,516.21	1,592.33	3,649.60
47	31,457	0.6	2,901.93	1,914.85	2,568.74	1,637.72	3,722.24
48	33,588	0.7	2,967.28	1,890.38	2,637.52	1,692.59	3,802.17
49	35,758	0.7	2,985.66	1,881.80	2,661.29	1,728.52	3,810.65
50	38,505	0.8	3,006.91	1,948.18	2,656.75	1,714.03	3,846.70
51	34,081	0.7	3,069.10	1,987.99	2,711.23	1,754.01	3,911.27
52	35,200	0.7	3,044.64	1,968.48	2,699.22	1,730.90	3,902.26
53	37,353	0.7	3,041.44	2,031.19	2,656.68	1,663.20	3,911.30
54	42,039	0.8	3,050.40	1,995.63	2,691.98	1,681.25	3,935.63
55	57,053	1.1	3,031.82	1,993.77	2,686.03	1,655.26	3,929.67
56	133,103	2.6	2,739.54	1,902.85	2,402.36	1,337.71	3,653.27
57	134,831	2.6	2,910.43	1,957.02	2,568.83	1,506.89	3,835.12
58	124,027	2.4	2,979.59	2,032.32	2,616.53	1,506.76	3,934.52
59	131,881	2.6	3,056.59	2,106.81	2,671.40	1,531.18	4,042.43
60	2,339,771	45.8	3,167.25	2,582.35	2,584.60	1,381.40	4,146.38
Total	5,110,629	100.0	2,668.61	2,167.89	2,126.24	1,223.35	3,471.50

TABLE 26A—FREQUENCY OF LENGTH OF 30-DAY PERIODS AND AVERAGE RESOURCE USE FOR EPISODES OF A CERTAIN LENGTH

Length of period in days	Number of periods	Percent of periods	Average resource use	Standard deviation of resource use	25th Percentile of resource use	Median resource use	75th Percentile of resource use
1	3,524	0.0	\$324.24	\$263.35	\$280.90	\$211.49	\$370.04
2	8,369	0.1	388.82	369.29	315.71	239.78	433.16
3	15,906	0.2	457.10	366.59	362.89	264.75	533.87
4	23,219	0.3	505.38	421.31	389.49	278.90	600.01
5	32,751	0.4	548.40	454.32	422.29	293.29	661.01
6	41,608	0.5	574.07	450.58	448.54	304.63	704.08
7	43,863	0.5	659.05	534.21	512.49	332.18	825.53
8	51,527	0.6	701.40	524.40	566.85	362.61	892.13
9	52,384	0.6	750.57	575.81	606.90	383.81	957.98
10	57,437	0.7	821.25	612.49	679.85	416.34	1,056.92
11	64,917	0.8	871.27	626.24	738.18	452.60	1,118.16
12	71,310	0.8	937.62	667.37	791.38	482.71	1,220.16
13	79,309	0.9	990.00	697.39	832.05	514.47	1,288.99
14	81,603	0.9	1,097.23	740.41	943.52	584.53	1,432.03
15	86,340	1.0	1,154.17	754.00	999.52	634.63	1,495.77
16	77,411	0.9	1,180.96	793.23	1,017.08	634.79	1,538.93
17	77,257	0.9	1,217.06	828.31	1,044.18	656.03	1,579.78
18	79,981	0.9	1,251.95	846.54	1,070.55	665.44	1,632.13
19	82,356	1.0	1,296.30	881.05	1,109.47	687.23	1,690.54
20	89,669	1.0	1,336.50	899.78	1,144.26	709.84	1,748.36
21	91,247	1.1	1,426.72	942.61	1,230.61	773.65	1,859.45
22	99,530	1.2	1,472.50	956.21	1,274.66	809.29	1,910.76
23	94,124	1.1	1,494.61	993.71	1,285.28	793.44	1,959.20
24	99,779	1.2	1,513.58	1,018.60	1,302.00	791.75	1,989.40
25	113,978	1.3	1,486.39	1,035.65	1,260.53	749.62	1,964.15
26	188,106	2.2	1,282.22	1,006.44	1,027.40	550.41	1,727.53
27	195,398	2.3	1,372.37	1,038.05	1,126.05	617.79	1,844.29
28	189,012	2.2	1,465.50	1,086.75	1,219.26	668.85	1,967.27
29	202,819	2.3	1,541.39	1,118.11	1,295.04	727.83	2,060.18
30	6,247,373	72.3	1,719.92	1,375.02	1,396.74	728.43	2,305.59
Total	8,642,107	100.0	1,585.48	1,289.23	1,262.65	671.96	2,119.49

The 60-day episode unit of payment was originally implemented on October 1, 2000, because most episodes in the HHA per-episode PPS demonstration, which was used to inform the development of the HH PPS, ended in 60 days or less, the OASIS data would be captured on a 60-day cycle, and Medicare plan of care/certification requirements continue to be bimonthly (64 FR 58143). In the FY 2001 HH PPS proposed rule, we noted that about 60 percent of episodes paid under the HH PPS were completed within one 60-day episode and 73 percent within two 60-day episodes. In the FY 2001 HH PPS final rule, we noted that we would continue to monitor the appropriateness of the 60-day unit of payment, and would consider modifying our approach to the episode definition in subsequent years of PPS, if warranted (65 FR 41136).

In CY 2016, 73 percent of episodes were completed within one 60-day episode and 86 percent within two 60-day episodes. We currently observe wide variation in the length of care in the current HH PPS. Overall, the average length of home health care was approximately 46 days, but roughly a

quarter of all 60-day episodes lasted 30 days or less. For example, those episodes that had a hospital stay in the seven days prior to the start of the episode where the Diagnosis Related Group (DRG) was either 469 or 470 (major joint replacement or reattachment of lower extremity) had an average length equal to 23.7 days. As noted above, there is a decline in visits as the episode proceeds with a 61.8 percent decline from the first 15 days of care in a 60-day episode to the last 15 days of care in a 60-day episode.

The wide variation in resource use and trends toward shorter episodes of care, the difference in resources between the first and second 30-day period within a 60-day episode, and the removal of the therapy visit thresholds from the case-mix adjustment methodology (which currently account for variation in resource use, but create adverse incentives as outlined in section II.D of this proposed rule) result in less accurate case-mix weights. When a shorter, more constrained time period is used for payment, the HHGM's goodness of fit statistics (for example, R-squared) improve due to reduced resource use variation. Accordingly, the

case-mix weights under the HHGM better approximate relative resource use. Therefore, we are proposing to change the unit of payment under section 1895(b)(2) of the Act from a 60-day episode of care to 30-day periods of care. Section 1895(b)(2) of the Act requires the Secretary to consider potential changes in the mix of services provided within that unit and their cost. Our analysis shows evidence of a change in the mix of services under a 60-day episode of care, as outlined above and in section II.D of this proposed rule. Therefore, to better account for changes in the mix of services over time; to ensure that the unit of payment reflects an appropriate number, type, and duration of visits provided within a unit of payment; and to provide continued access to quality services, we are proposing to change the unit of payment from a 60-day episode of care to a 30-day period of care and to implement case-mix adjustment methodology refinements, outlined in sections III.E.1 through III.E.12 of this proposed rule.

b. National, Standardized 30-Day Payment Amount

We note that we propose to implement the HHGM for 30-day periods of care beginning on or after January 1, 2019.²⁶ As a result, we would calculate a proposed national, standardized 30-day payment amount in the CY 2019 HH PPS proposed rule. In calculating a national, standardized 30-day payment amount for CY 2019, we propose to start with the CY 2019 national, standardized 60-day episode payment amount reflecting the HHA market basket update as specified in section 1895(b)(3)(B) of the Act, add back in the CY 2019 non-routine medical supply (NRS) conversion factor amount reflecting the HHA market basket update as specified in section 1895(b)(3)(B) of the Act, and then divide the sum by two.

If we had proposed to implement the HHGM in CY 2018, we would have calculated a proposed 30-day payment amount for CY 2018 by starting with the CY 2018 proposed national, standardized 60-day episode payment amount of \$3,038.43, adding back in the CY 2018 proposed NRS conversion factor amount of \$53.03, and dividing the sum by two to produce a 30-day payment amount of \$1,545.73. However, we reiterate that we propose to implement the HHGM for 30-day periods of care beginning on or after January 1, 2019; so we propose to

calculate a national, standardized 30-day payment amount for CY 2019 using the CY 2019 60-day episode payment amount, adding back in the CY 2019 NRS conversion factor and dividing the sum by two to produce a 30-day payment amount. Finally, we note that the calculation proposed above would only be used to calculate a national, standardized 30-day payment amount for CY 2019. To calculate a national, standardized 30-day payment amount for CY 2020 and subsequent years, we would update the national, standardized 30-day payment amount from the immediate preceding year by the home health payment update percentage required by the statute, as described in section III.C.1 of this rule.

In determining the 30-day payment amount, we evaluated whether starting with the national, standardized 60-day episode payment amount, adding back in the NRS conversion factor amount and dividing the sum by two was an appropriate estimate of the cost of a 30-day period of care. Section 1895(b)(3) of the Act provides a methodology for determining an initial payment amount for the PPS and for calculating annual increases. As noted in this proposed rule, the Act at section 1895(b)(2) gives the Secretary the discretion to determine the “unit of payment” (also referred to in the statute as a “unit of service”) on which a standard prospective payment amount would be

based. Since we are proposing to change the unit of payment, we believe it is necessary to calculate a 30-day payment amount that would accurately reflect what a 30-day payment would be had we chosen to use a 30-day rather than a 60-day unit of payment when we first implemented the PPS.

To do this, we calculated an estimated 30-day payment amount by taking the average number of visits per discipline per 30-day period of care in CY 2016 multiplied by the FY 2001 per-visit amounts (including average NRS costs per visit) initially established under the HH PPS based on the most recent audited cost report data available to the Secretary in accordance with section 1895(b)(3)(A)(I) of the Act, as adjusted for inflation and productivity. The FY 2001 per-visit amounts were adjusted for inflation by the actual HHA market basket updates (reflecting historical data from FY 2002 to CY 2016), the regulatory HHA market basket updates for CY 2017 (which is based on the CY 2017 forecasted data at the time of CY 2017 rulemaking (81 FR 76714)) and CY 2018 (which is based on the CY 2018 forecasted data in this CY 2018 proposed rule), and for productivity (using Economy-wide Multifactor Productivity as specified in section 1895(b)(3)(B)(vi) to the Act and described in section 1886(b)(3)(B)(xi)(II) of the Act) beginning in 2015, as reflected in Table 26B.

TABLE 26B—HHA MARKET BASKET UPDATES AND PRODUCTIVITY ADJUSTMENTS, FY 2002 THROUGH CY 2018

	FY 02	FY 03	FY/CY 04*	CY 05	CY 06	CY 07	CY 08	CY 09	CY 10
Market Basket Update (Historical Data FY02 to CY16, forecast CY17 and CY18)	3.4	3.2	4.0	3.1	3.1	3.5	3.2	1.7	1.7
	CY 11	CY 12	CY 13	CY 14	CY 15	CY 16	CY 17	CY 18	
Market Basket Update (Historical FY02 to CY16, forecast CY 17 and CY 18)	2.0	1.7	1.6	1.6	1.6	2.0	2.8	2.7	
Multi-Factor Productivity Adjustment (historical CY15, preliminary historical CY16, forecast CY17 and CY18)					0.4	0.6	0.3	0.5	

As shown in Table 28, using the FY 2001 per-visit amounts initially established under the HH PPS results in an estimated 30-day payment amount of \$1,494.64. This value is less than, but similar to half the sum of the proposed CY 2018 national, standardized 60-day episode payment amount and proposed CY 2018 NRS conversion factor amount (\$1,545.73).

We also calculated an estimated 30-day payment amount by taking the

average number of visits per discipline per 30-day period of care in CY 2016 multiplied by the FY 2015 costs-per-visit, per discipline, based on the most recent cost report data available at the time of CY 2018 HH PPS rulemaking (as outlined in Table 2 in section III.A of this proposed rule) and further adjusted to include average NRS costs per visit, for outliers in accordance with section 1895(b)(3)(C) of the Act, and for inflation and productivity. As shown in

Table 29, using 2015 costs-per-visit, per discipline, based on the most recent cost report data available at the time of CY 2018 HH PPS rulemaking, results in an estimated 30-day payment amount of \$1,485.11. This value is also less than, but similar to half the sum of the proposed CY 2018 national, standardized 60-day episode payment amount and proposed CY 2018 NRS conversion factor amount (\$1,545.73).

²⁶ 60-day episodes of care that begin on or before December 31, 2018 and end on or after January 1, 2019, will be paid using the current case-mix

adjustment methodology (153-group system) and a CY 2019 national, standardized 60-day episode

payment amount and/or CY 2019 national per-visit amounts.

TABLE 27—AVERAGE VISITS PER DISCIPLINE FOR 30-DAY PERIODS OF CARE, CY 2016

Discipline	CY 2016 Average number of visits in 30-day period
Skilled Nursing	5.0
Physical Therapy	3.3
Occupational Therapy	0.9
Speech-Language Pathology	0.2
Medical Social Services	0.1

TABLE 27—AVERAGE VISITS PER DISCIPLINE FOR 30-DAY PERIODS OF CARE, CY 2016—Continued

Discipline	CY 2016 Average number of visits in 30-day period
Home Health Aides	1.0

TABLE 27—AVERAGE VISITS PER DISCIPLINE FOR 30-DAY PERIODS OF CARE, CY 2016—Continued

Discipline	CY 2016 Average number of visits in 30-day period
Total	10.5

Source: CY 2016 claims data (as of March 17, 2017), excluding 30-day periods of care with no visits and those classified as LUPAs as outlined in section III.E.9 of this proposed rule.

TABLE 28—ESTIMATED 30-DAY PAYMENT AMOUNT IN CY 2018 (USING FY 2001 HH PPS PER-VISIT AMOUNTS, PER DISCIPLINE, ADJUSTED FOR INFLATION AND FOR PRODUCTIVITY BEGINNING IN 2015)

Discipline	FY 2001 per-visit amounts ¹	FY 2001 per-visit amounts trended forward to 2018	CY 2016 average number of visits in 30-day period	CY 2018 30-day period costs
Skilled Nursing	\$95.34	\$143.03	5.0	\$715.15
Physical Therapy	104.27	156.43	3.3	516.22
Occupational Therapy	104.97	157.48	0.9	141.73
Speech-Language Pathology	113.32	170.01	0.2	34.00
Medical Social Services	152.95	229.47	0.1	22.95
Home Health Aides	43.05	64.59	1.0	64.59
Total			10.5	1,494.64

¹ The FY 2001 per-visit amounts can be found in 65 FR 41187 through 41188 (Table 6).

Note(s): When the HH PPS was established on October 1, 2000, the original per-visit payment amounts for each discipline included a one-time adjustment of \$0.21 to reflect the costs associated with OASIS assessment schedule refinements (65 FR 41187). In addition, the resulting per-visit rates were then divided by 1.05 to account for the estimated percentage of outlier payments, a calculation further refined in the CY 2008 HH PPS final rule (72 FR 49868) by multiplying by 1.05 and 0.95. The FY 2001 per-visit amounts in the text reflect removing the \$0.21 from the FY 2001 per-visit amounts and include the effects of the CY 2008 outlier calculation refinement.

TABLE 29—ESTIMATED 30-DAY PAYMENT AMOUNT IN CY 2018 (USING FY 2015 AVERAGE COSTS-PER-VISIT, PER DISCIPLINE, ADJUSTED FOR INFLATION AND FOR PRODUCTIVITY BEGINNING IN 2015)

Discipline	FY 2015 average costs-per-visit	FY 2015 average NRS costs-per-visit ¹	FY 2015 average NRS costs-per-visit plus NRS	FY 2015 average costs-per-visit plus NRS trended forward to 2018	Outlier adjustment factor	CY 2016 average number of visits in 30-day period	CY 2018 30-day period costs
Skilled Nursing	\$132.48	+\$3.36	\$135.84	\$144.29	× 0.95	5.0	\$685.38
Physical Therapy	156.32	3.36	159.68	169.61	× 0.95	3.3	531.73
Occupational Therapy ..	154.64	3.36	158.00	167.83	× 0.95	0.9	143.50
Speech-Language Pathology	170.96	3.36	174.32	185.17	× 0.95	0.2	35.18
Medical Social Services	220.07	3.36	223.43	237.33	× 0.95	0.1	22.55
Home Health Aides	62.80	3.36	66.16	70.28	× 0.95	1.0	66.77
Total						10.5	1,485.11

¹ Of the 8,032 FY 2015 HHA cost reports used for the analysis presented in Table 2 in section III.A of this proposed rule, NRS costs totaled \$301,207,702. For those same 8,032 HHAs, visits (all visits, all episode types) where the claim through date fell on or between the FY start end date of the agency's cost report totaled 89,726,272. \$301,207,702 divided by 89,726,272 = \$3.36 per visit.

We believe our proposal to start with the national, standardized 60-day episode payment amount, add back in NRS conversion factor amount, and then divide the sum by two is a reasonable estimate of the cost of a 30-day period of care. We propose to implement the change in the unit of payment from 60-day episodes of care to 30-day periods of care in a non-budget neutral manner. We note that in its March 2017 Report

to Congress, MedPAC highlighted that home health payments have consistently and substantially exceeded costs because agencies are able to reduce the number of visits provided and cost growth is generally lower than the annual payment updates for home health care.²⁷ MedPAC recommended a

²⁷ Medicare Payment Advisory Commission (MedPAC). "Home Health Care Services." *Report to Congress: Medicare Payment Policy*. Washington,

5 percent reduction in the base rate for 2018 and a 2-year rebasing beginning in 2019.²⁸ We invite comments on the proposed calculations for determining the 30-day payment amount, including our rationale for proposing to

DC, March 2017. P. 232. Accessed on July 16, 2017 at: http://www.medpac.gov/docs/default-source/reports/mar17_medpac_ch9.pdf?sfvrsn=0.

²⁸ Ibid.

implement the HHGM in a non-budget neutral manner.

We are further proposing to implement the HHGM in a fully non-budget neutral manner beginning in CY 2019 or alternatively to use a phased approach to implementation. We acknowledge that implementing the HHGM in a partially budget-neutral manner could lessen the economic impact for HHAs in transitioning to the HHGM. Therefore, we considered potential alternative implementation approaches for the HHGM, including, but not limited to, a partially budget-neutral approach with a phase-out period. Specifically, for the phased approach, we propose to apply a HHGM partial budget neutrality adjustment factor in CY 2019 that would reduce the estimated impact of the HHGM from an estimated -4.3 percent to -2.2 percent in the initial year of implementation with the removal of the HHGM partial budget neutrality adjustment factor in CY 2020. We invite comments on whether to implement the HHGM in a fully non-budget neutral manner beginning in CY 2019; whether to alternatively implement the HHGM in CY 2019 with a HHGM partial budget neutrality adjustment factor applied and then subsequently removed in CY 2020; or whether a HHGM partial budget neutrality adjustment factor should be applied and then phased-out over a longer period of time.

c. Split Percentage Payment Approach for 30-Day Periods of Care

In the current HH PPS there is a split percentage payment approach to the 60-day episode. The first bill, a Request for Anticipated Payment (RAP), is submitted at the beginning of the episode. The second, final bill is submitted at the end of the 60-day episode of care. An initial percentage payment of 60 percent of the anticipated final claim payment amount is paid at the beginning of the episode and a final percent payment of 40 percent is paid at the end of the episode. For all subsequent episodes for beneficiaries who receive continuous home health care, the episodes are paid at a 50/50 percentage payment split. A new initial and final bill must be submitted for each 60-day episode period. HHAs are encouraged to submit the RAP as soon as possible after care begins to assure being established as the primary HHA for the beneficiary and so that the claims processing system is alerted that a beneficiary is under a HH episode of care to enforce the consolidating billing edits required by law.

We are not proposing a change to the split percentage payment approach in

conjunction with proposing to change the unit of payment from a 60-day episode to a 30-day period of care. Under the proposed HHGM, we propose that the initial payment for initial 30-day periods would be paid at 60 percent of the case-mix and wage-adjusted 30-day payment rate. The residual final payment for initial 30-day periods would be paid at 40 percent of the case-mix and wage-adjusted 30-day payment rate. We propose the initial payment for subsequent 30-day periods would be paid at 50 percent of the case-mix and wage-adjusted 30-day payment rate. The residual final payment for subsequent 30-day periods would be paid at 50 percent of the case-mix and wage-adjusted 30-day payment rate.

However, we note the length of time HHAs currently take to submit the RAP indicates that the RAP payment might not be necessary for the majority of HHAs to maintain an adequate cash flow (see Table 30). Approximately 5 percent of RAPs (95th percentile) are not submitted until the end of an episode of care and the median length of days for RAP submission is 12 days from the start of the episode. In addition, eliminating RAP payments would address existing program integrity vulnerabilities. For example, \$1.8 billion in RAP payments (July 1, 2015 through July 31, 2016) were auto-cancelled, and of that amount, a final claim was never submitted for \$321 million worth of RAP payments.²⁹

TABLE 30—NUMBER OF DAYS FROM THE START OF CARE TO INITIAL RAP SUBMISSION

Percentile	Number of days from the start of care to initial RAP submission
1	1
10	5
25	8
50	12
75	21
90	36
95	57
99	169

Source: Analysis of CWF data from July 1, 2015 through July 31, 2016 and HIGLAS payments and recoupments.

We are soliciting comments as to whether the split payment approach would still be needed for HHAs to maintain adequate cash flow if the unit of payment changes from 60-day

²⁹ A RAP is auto-cancelled and recouped on the next disbursement if the final claim is not received within 4 months of the start of care or within 2 months of when the RAP was paid (whichever is greater).

episodes to 30-day periods of care under our proposal. In addition, we are soliciting comments on ways to phase-out the split percentage payment approach in the future if the proposed HHGM is finalized with the split percentage payment approach being initially maintained. Specifically, we are soliciting comments on reducing the percentage of the upfront payment over a period of time. We believe that payment based on 30-day periods would reduce, if not eliminate, the need for these partial, up-front payments that occur in the current payment system. Home health agencies would bill on a monthly basis, similar to hospices and SNFs, and thus receive final payment sooner.

If in the future the split percentage approach was eliminated, we are also soliciting comments on the need for HHAs to submit a notice of admission within 5 days of the start of care to assure being established as the primary HHA for the beneficiary and so that the claims processing system is alerted that a beneficiary is under a HH period of care to enforce the consolidating billing edits required by law.

We invite comments on the proposed change in the unit of payment from a 60-day episode of care to a 30-day period of care under the HHGM; the calculation of the national, standardized 30-day payment amount, initially maintaining the split percentage payment approach and applying such policy to 30-day periods of care; and the associated regulations text changes outlined in section III.E.13. of this proposed rule. We are also soliciting comments on ways the split percentage payment approach could be phased-out and whether to implement a notice of admission process if the split percentage payment approach is eliminated in the future.

4. Episode Timing Categories

To advance the goals of better aligning payment with patient needs, as well as addressing payment incentives and vulnerabilities within the current system, we investigated the impact of episode timing on home health resource use. In the current payment system, 60-day episodes are classified as “early” if they are the first or second in a sequence of episodes and “late” if they are the third or later in the sequence. Episodes are defined as being in the same sequence if there are no more than 60 days between the end of one episode and the start of the next. In the development of the proposed HHGM, we sought to evaluate whether payments to providers appropriately reflect the varying resource needs of

home health beneficiaries during various portions of the home health stay, accounting for contrasting patient characteristics.

We endeavored to evaluate whether beneficiaries in their first 30-day period of care have different needs and patterns of resource use than those in later 30-day periods, thus possibly resulting in the potential need for differentiated payment amounts. We reviewed related research, held technical and clinical expert panels, and performed our own investigative analyses. In particular, we were interested in whether home health patients utilize more resources at the beginning of home health than in later periods of the home health stay, and, if so, does the current payment structure sufficiently account for this elevated need. In a review of research related to episode timing, studies show that more frequent skilled visits in the first few weeks of a home health stay can prove beneficial for certain diagnoses by reducing the likelihood of readmission to an institutional setting and easing the transition from hospital to home, which can be challenging for patients.

The Visiting Nurse Associations of America defines “frontloading” as the practice of providing an increase in intensity of visits during the first two to three weeks of the home health care episode for patients that have been determined to be at high risk for hospitalization.³⁰ A 2014 literature review titled “Frontloading and Intensity of Skilled Home Health Visits: A State of the Science” found that Medicare patients benefited from an intensified level of care through a “frontloading” approach, which reduced the need for re-hospitalization among skilled home health patients, and especially for those with heart failure.³¹ For the purposes of this particular study, frontloading was defined as providing 60 percent of planned visits within the first 2 weeks of the home health episode of care. Furthermore, frontloading was also found by the Briggs® National Quality Improvement/Hospitalization Reduction Study,³² to

be one of 15 best practices routinely employed by 64 percent of the HHAs who were most successful at reducing hospitalizations. Similarly, in an article titled “The Effect of Frontloading Visits on Patient Outcomes,”³³ the authors assessed the impact of frontloading on patients with insulin-dependent diabetes and with heart failure. In their research, the authors found that frontloading was effective for patients with heart failure, decreasing re-hospitalization by more than half (39.4 percent vs. 16 percent), with fewer visits overall (15.5 vs. 9.5) and equal clinical outcomes and patient satisfaction. These improvements in overall outcomes were presumably due to the timing of the services, where more visits were provided in the beginning portion of the episode, even when fewer visits were provided overall. However, we note that there was no significant impact for those patients with diabetes. No specific effect for patients with mental health or behavioral health conditions was noted. Given the potential positive outcomes of the practice of frontloading, specifically for those beneficiaries with heart disease, we expect that HHAs would provide more frequent skilled services in the beginning portion of a home health stay to educate patients in medication management, coordinate the instruction of both the patient and family, and support patients in navigating their clinical situation, especially in cases of heart disease. The first and fourth reported top primary reasons for home health care in CY 2016 were hypertension and heart failure, respectively, and we therefore believe an opportunity exists for HHAs to improve the outcomes for these high-volume home health beneficiaries by providing more resources in the early period of a home health stay.

For many patients admitted to home health, the transition from hospital or other institutional settings back to the home environment can be very challenging and lead to adverse effects for the beneficiary, such as medication errors, harmful drug events, and additional complications. The provision of intensified home health services early

in a home health stay can potentially help to mitigate any negative events that could result from this time of transition from the institutional setting to the home. As such, we would expect that beneficiaries would require more resources, particularly from skilled disciplines providing teaching and medication management, during the first 30 days of a home health admission.

As described in section III.E.3 of this proposed rule, analysis of home health data demonstrates that HHAs provide more services in the first 30-day period of home health than in later periods of care. The differences in the resource utilization during home health episodes are presented in Table 22, which shows the average resource use of home health episodes divided into 15-day segments. The first two 15-day periods in a home health episode have significantly higher average resource use at \$261.97 and \$162.44, respectively, as compared with the third and fourth 15-day segments in a 60-day period, at \$107.49 and \$88.67, respectively. Additionally, the average number of visits by the six disciplines is also significantly higher in the first two 15-day segments, at 6.8 and 4.9 visits per segment, respectively as compared to the third and fourth 15-day segments of a 60-day episode, at 3.3 and 2.6, respectively.

Further analysis of home health data demonstrates that under the current payment system, when analyzed by 30-day periods, HHAs provide more resources in the first 30-day period of home health (“early”) than in later periods of care. The differences in the average resource use during early and late home health episodes when divided into 30-day periods are presented in Table 28, and shows the first 30-day periods in a home health sequence have significantly higher average resource use at \$2,102.29 as compared with subsequent 30-day periods. Specifically, the later 30-day periods showed an average resource use of \$1,348.18, a difference of more than \$700 or a 36 percent decrease. Table 31 also shows a significant difference between the early and late episode median values of resource use. The median for the first 30-day period is \$1,848.12, while the median for subsequent 30-day periods is \$987.54, a difference of more than \$850 or an approximately 47 percent decrease.

³⁰ Care-Initiation-Frontloading. (n.d.). Retrieved March 20, 2017, from <http://vnaablueprint.org/Care-Initiation-Frontloading.html>.

³¹ O'Connor, M., Bowles, K.H., Feldman, P. H., Pierre, M. S., Jarrin, O., Shah, S., & Murtaugh, C. M. (2014). Frontloading and Intensity of Skilled Home Health Visits: A State of the Science. Retrieved March 02, 2017, from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4532304/>.

³² Briggs National Quality Improvement/Hospitalization * * * (n.d.). Retrieved March 2,

2017, from <http://www.briggscorp.com/ACHstrategies/BriggsStudy.pdf>.

³³ Rogers, J., Perlic, M., & Madigan, E. A. (2007). The Effect of Frontloading Visits on Patient Outcomes. *Home Healthcare Nurse: The Journal for the Home Care and Hospice Professional*, 25(2), 103–109. doi:10.1097/00004045-200702000-00011; <https://www.ncbi.nlm.nih.gov/pubmed/17285038>.

TABLE 31—AVERAGE RESOURCE USE BY TIMING (30 DAY PERIODS)

Timing	Average resource use (\$)	Number of episodes	Percent of episodes (%)	Standard deviation of resource use (\$)	25th percentile of resource use (\$)	Median resource use (\$)	75th percentile of resource use (\$)
Early Episodes	2,102.29	2,719,495	31.47	1,265.68	1,213.51	1,848.12	2,681.90
Late Episodes	1,348.18	5,922,612	68.53	1,229.14	537.85	987.54	1,760.20
Total	1,585.48	8,642,107	100.00	1,289.23	671.96	1,262.65	2,119.49

There is significant difference in the resource utilization between early and late 30-day periods as demonstrated in Table 31. Moreover, the predictive power of the HHGM in terms of estimating resource utilization improved when separating episodes into 30-day periods rather than 60-day periods (that is, the first and second 30-day periods). We believe that an HHGM that accounts for the demonstrated increase in resource utilization in the first 30-day period better captures the variations in resource utilization and further promotes the goal of payment accuracy within the HH PPS. We are proposing to classify the 30-day periods under the proposed HHGM as “early” or “late” depending on when they occur within a sequence of 30-day periods. For the purposes of defining “early” and “late” periods for the proposed HHGM, we are proposing that only the first 30-day period in a sequence of periods be defined as “early” and all other subsequent 30-day periods would be considered “late”. Additionally, we are proposing that the definition of a “home health sequence” (as currently described in § 484.230) will remain unchanged relative to the current system, that is, 30-day periods are considered to be in the same sequence as long as no more than 60 days pass between the end of one period and the start of the next, which is consistent with the definition of a “home health spell of illness” described at section 1861(tt)(2) of the Act. We note that because section 1861(tt)(2) of the Act is a definition related to eligibility for home health services as described at section 1812(a)(3) of the Act, it does not affect or restrict our ability to propose a 30-day prospective payment period.

To identify the first 30-day period within a sequence, the Medicare claims processing system would verify that the claim “From date” and “Admission date” match. If this condition were to be met, our systems would send the “early” indicator to the HH Grouper for the 30-day period of care. When the claim is received by CMS’s Common Working File, the system would look back 60 days to ensure there is not a

prior, related episode. If not, the claim would continue to be paid as “early.” If another related episode were to be identified, that is an earlier 30-day period in the sequence, the claim would be returned to the shared systems for subsequent regrouping and re-pricing. Those periods that are not the first 30-day period in a sequence of adjacent periods, separated by no more than a 60 day gap, would be categorized as “late” periods and placed in corresponding HHGM categories.

We invite public comments on the timing categories in the proposed HHGM and the associated regulations text changes outlined in section III.E.13 of this proposed rule.

5. Admission Source Category

In accordance with the statute, as amended by the BBA, we published a final rule in the July 3, 2000 **Federal Register** (65 FR 41128) implementing the HH PPS. In that final rule, we discussed and finalized the use of a methodology that included variables identifying pre-admission location (that is, whether certain inpatient and other stays occurred in the 14-day period immediately preceding the home health episode) as part of our case-mix adjustment methodology. We stated that not only were pre-admission inpatient stays a traditional indication of need in clinical practice, but also that such variables were useful correlates of resource cost in our evaluation of the home health case-mix data (65 FR 41146). This pre-admission information was submitted by HHAs via OASIS assessments.

In the CY 2008 HH PPS final rule, we removed elements from the case-mix adjustment methodology that were based upon the source of admission (72 FR 49766). In the CY 2008 HH PPS proposed and final rules, we assessed variables for policy and payment appropriateness and ultimately decided to remove the variable that had been used to identify the patient’s pre-admission location from the case-mix adjustment methodology (72 FR 25361 and 72 FR 49766, respectively). This decision was based, in part, upon concerns that some agencies were

encountering challenges in obtaining concrete information regarding the patient’s preadmission location while performing the initial home health assessment and thus the OASIS item used to indicate the preadmission location of the patient was not always reliable. Moreover, the pre-admission information did not perform well in terms of the four-equation model used for payment estimation and also had a small impact in terms of payment accuracy within the model. In the CY 2008 HH PPS final rule, we further noted that the item’s results across the four equation model created difficulties in terms of interpretation and the explanatory power (for example, its contribution to the R-squared value) was minimal (72 FR 49766).

For the purposes of constructing the HHGM, which would not use a 4-equation model or otherwise adjust payments based on therapy visit thresholds; we reexamined the impact of beneficiary admission source, either from the community or from an institutional setting, on home health resource use. In our review of related scholarly research, we found that beneficiaries admitted directly or recently from an institutional setting (acute or post-acute care (PAC)) tend to have different care needs and higher resource use than those admitted from the community, thus indicating the need for differentiated payment amounts. For instance, a literature review of 25 research studies published between 2002 and 2011, titled “Hospitalization Among Medicare-Reimbursed Skilled Home Health Recipients,” found that Medicare beneficiaries discharged from PAC and acute facilities differ significantly in resource need when compared to community-admitted beneficiaries.³⁴ Patients discharged from acute and PAC settings tend to be sicker upon admission and are being discharged rapidly back to the community. Additionally, they are more likely to be

³⁴ O’Connor, M. (2012, February). Hospitalization Among Medicare-Reimbursed Skilled Home Health Recipients. Retrieved March 02, 2017, from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4690459>.

re-hospitalized after discharge due to the acute nature of their illness. One study discussed in this literature review determined that patients being discharged from an inpatient hospitalization typically present with multiple comorbidities, suggesting that initially-hospitalized patients subsequently transferred to home care were more likely to have four or more secondary diagnoses, as well as a pressure or stasis ulcer, urinary incontinence, a urinary catheter, depression, or dyspnea.³⁵ They generally had more than five medications than their non-hospitalized counterparts and required assistance with medication management.³⁶ As such, patients referred to home health after an institutional stay tend to be more infirm, requiring significant resources upon admission to home health. Additionally, the same literature review also highlighted a study titled “Unplanned hospital readmissions: A home care perspective” that demonstrated that patients referred from acute and PAC settings are at a high risk of hospitalization within 14 to 21 days of admission to home health.³⁷ Given that the first few weeks after an institutional stay represent a critical window in terms of providing beneficiaries with appropriately intensive supports and services, as well as preventing re-hospitalization, we would expect that providing care for those beneficiaries admitted from institutional settings would require more resource use compared to patients admitted to home health from the community. Comprehensive and deliberate interventions in this timeframe could also potentially reduce re-hospitalization rates.

Research studies also demonstrate that patients admitted to home health from institutional settings are more vulnerable to adverse effects and injury because of the functional decline that occurs as a result of their institutional stay, indicating that this patient population requires more concentrated resources and supports to account for and mitigate this functional decline. In

the article titled “The Incidence and Severity of Adverse Events Affecting Patients after Discharge from the Hospital,”³⁸ Alan J. Forster, MD noted that beneficiaries are susceptible to harm post-hospitalization: “Patients may be especially vulnerable to injuries during this [post-discharge] period because they may still have functional impairments and because discontinuities may occur at the interface of acute and ambulatory care.” The author also notes that the current health care environment encourages potentially expedited discharges from hospital stays, “in which patients are leaving the hospital ‘quicker and sicker.’” Patients may be leaving the hospital environment in a tenuous and fragile state, leaving them vulnerable to further harm once returned to the home environment. Additionally, the change from constant monitoring in the inpatient facility to less frequent monitoring in the home environment can potentially cause gaps in care and consequently increased risk for adverse events for the newly-admitted home health beneficiary. The article notes that many of the negative impacts of the transition can be reduced by an appropriate increase in care for the beneficiary in the home setting, notably with more frequent assessment of their condition and ongoing monitoring. Therefore, we believe that an opportunity may exist for the HHGM to account for this increased need and accordingly provide a differentiated payment to facilitate the provision of more frequent assessments and monitoring for beneficiaries admitted to home health from acute and PAC settings, which could in turn help prevent re-hospitalizations and adverse events. We expect that HHAs would provide more resource-intensive services after discharge from an institutional setting to educate patients in new medication management, facilitate discharge education for the patient and family, and provide support in the recovery from the illness that caused the originating hospitalization or institutional stay.

In the guidebook “Patient Safety and Quality: An Evidence-based Handbook for Nurses,” authors Ruth M. Kleinpell, Kathy Fletcher, of and Bonnie M. Jennings note in chapter 11 that deconditioning, a status characterized by a “decrease in muscle mass and the other physiologic changes related to bed

rest, contributes to overall weakness,” has become commonplace in the post-institutional beneficiary population.³⁹ This physiological weakening of the institutionalized beneficiary can then, in turn, lead to significant functional decline, resulting in reduction in ability to perform Activities of Daily Living (ADLs), and ultimately in increased home health resource utilization. The article notes that hospitalization of the elderly is usually marked by decreased levels of mobility and increased levels of bed rest, with deterioration from their baseline levels as soon as day two of the hospitalization. Hence, a hospitalization itself leads to declines in mobility, which consequently yields reduced functionality in patients relative to their status before their inpatient stay. This decline in functional ability likewise merits appropriate skilled services to support the patient’s increased needs after a hospital stay.

In the article “Determinants of health after hospital discharge: Rationale and design of the Vanderbilt Inpatient Cohort Study (VICS),” the authors describe the period after a hospitalization as a “vulnerable time” for patients.⁴⁰ This vulnerability is due to a number of factors, including the need to manage new health care issues, major modifications to medication interventions, and the coordination of follow-up appointments, all while a beneficiary strives to recuperate after a hospital stay for an acute medical event. Of particular concern are the risks for adverse drug events, for errors in a beneficiary’s medication regimen, and for the need to readmit to the hospital due to deterioration of the patient’s condition. Given the risks during this intense, challenging, and potentially costly period after discharge, we would expect that beneficiaries would require more visits from skilled disciplines, particularly for the purpose of teaching and medication management. This increased utilization of resources would, in turn, warrant a differentiated, potentially higher payment for such services, and the proposed HHGM payment system refinement could account for this difference with varying

³⁵ Rosati, R. J., Huang, L., Navaie-Walser, M., & Feldman, P. H. (2003). Risk Factors for Repeated Hospitalizations Among Home Healthcare Recipients. *Journal For Healthcare Quality*, 25(2), 4–11. doi:10.1111/j.1945–1474.2003.tb01038.x.

³⁶ Rosati, R. J., Huang, L., Navaie-Walser, M., & Feldman, P. H. (2003). Risk Factors for Repeated Hospitalizations Among Home Healthcare Recipients. *Journal For Healthcare Quality*, 25(2), 4–11. doi:10.1111/j.1945–1474.2003.tb01038.x.

³⁷ Anderson, M. A., Helms, L. B., Hanson, K. S., & Devilder, N. W. (1999). Unplanned Hospital Readmissions: A Home Care Perspective. *Nursing Research*, 48(6), 299–307. doi:10.1097/00006199-199911000-00005.

³⁸ Forster, A.J. (2003). The Incidence and Severity of Adverse Events Affecting Patients after Discharge from the Hospital. *Annals of Internal Medicine*, 138(3), 161. doi:10.7326/0003-4819-138-3-200302040-00007.

³⁹ Hughes, R. (2008). Patient safety and quality: An evidence-based handbook for nurses. Rockville, MD: Agency for Healthcare Research and Quality, U.S. Dept. of Health and Human Services. <https://archive.ahrq.gov/professionals/clinicians-providers/resources/nursing/resources/nurseshrdbk/nurseshrdbk.pdf>, 259–274.

⁴⁰ Meyers, A.G., Salanitro, A., Wallston, K.A., Cawthon, C., Vasilevskis, E.E., Goggins, K. M., . . . Kripalani, S. (2014). Determinants of health after hospital discharge: Rationale and design of the Vanderbilt Inpatient Cohort Study (VICS). *BMC Health Services Research*, 14(1). doi:10.1186/1472-6963-14-10.

payment amounts based upon admission source. We note that we do not expect the source of the patient's admission would lead to an HHA furnishing home health services that would replace any orders made by the referring physician regarding the type or frequency of services the patient might need during the home health stay. The admission source variable in the proposed HHGM is meant to serve as a meaningful indicator of resource utilization, which determines Medicare payment. The HHA, in consultation with the physician and ordered by the physician, will continue to articulate, in the plan of care, what services are required to meet the needs of the patient, as well as the frequency of such services.

With regard to beneficiaries admitted to home health from the community, research related to home health admission source demonstrates that community-admitted beneficiaries tend to receive care from the less-costly disciplines. In its 2016 Report to Congress, MedPAC noted that, in their analysis of CY 2013 HH claims, beneficiaries admitted from the community tend to receive more visits from home health aides than their non-community counterparts, stating that

“aide services were the majority of services provided in 14 percent of the episodes for community-admitted users compared with 5 percent for PAC users.”⁴¹ However, these same community entrants averaged 2.6, 60-day episodes, while the institutional admits averaged only 1.4, 60-day episodes, demonstrating longer lengths of stay for the community-admitted beneficiaries than those entering from institutional settings. These findings suggest that beneficiaries admitted to home health from the community typically require less resources but for longer periods of time when compared to the beneficiaries admitted from an institutional stay. Additionally, a 2001 Department of Health and Human Services Office of Inspector General study found Medicare home health referrals coming from the community (in this case defined as a referral for a beneficiary who had not been admitted to an overnight stay in a hospital or skilled nursing facility for 15 days prior to beginning a home health care episode) were more likely to have chronic conditions than those referred from hospitals, and therefore, were more likely to require ongoing but less resource-intensive care.⁴²

In addition to our review of related research, we also evaluated home health utilization and patient assessment data as described in section III.E.1 of this proposed rule, and our findings demonstrate that those beneficiaries admitted from PAC, as well as acute care settings demonstrate higher resource utilization than their community-admitted counterparts.

The differences in care needs during home health based on admission source are illustrated in the resource utilization figures presented in Table 32, which shows the distribution of admission sources as well as average resource use for 30-day periods by admission source. Institutional admissions have significantly higher average resource use at \$2,165.06 compared with community admissions at \$1,393.10, a difference of \$771.96. Median values of resource use also show a significant difference between sources of admission, with institutional resource use at \$1,899.41 while community resource use is at \$1,060.51, a difference of nearly \$840. The pattern of higher resource use for institutional admissions as compared to community admissions continues for the 25th and 75th percentiles, with a difference of approximately \$700 and \$900, respectively.

TABLE 32—AVERAGE RESOURCE USE BY ADMISSION SOURCE (14 DAY LOOK-BACK) ADMISSION SOURCE

	Average resource use	Number of 30-day periods	Percent of 30-day periods	Standard deviation of resource use	25th percentile of resource use	Median resource use	75th percentile of resource use
Institutional	\$2,165.06	\$2,153,712	24.92	\$1,350.43	\$1,224.83	\$1,899.41	\$2,772.04
Community	1,393.10	6,488,395	75.08	1,208.29	571.97	1,060.51	1,838.39
Total	1,585.48	8,642,107	100.00	1,289.23	671.96	1,262.65	2,119.49

Source: CY 2016 Medicare Home Health Claims Data (as of March 17, 2017).

For all of these reasons, we are proposing to establish two admission source categories for grouping 30-day periods of care under the HHGM—institutional and community—as determined by the healthcare setting utilized in the 14 days prior to home health admission. We are proposing the institutional category would include 30-day periods of care for patients admitted from either acute care or PAC settings. Thirty-day periods for beneficiaries with any inpatient acute care hospitalizations, skilled nursing facility stays, inpatient rehabilitation facility stays, or long term care hospital stays within the 14 days prior to a home

health admission would be designated as institutional admissions. Similarly, we are proposing that the institutional admission source category would also include patients that had an acute care hospital stay during a previous 30-day period of care and within 14 days prior to the subsequent, contiguous 30-day period of care and for which the patient was not discharged from home health and readmitted (that is, the admission date and from date for the subsequent 30-day period of care do not match) as we acknowledge that HHAs have discretion as to whether they discharge the patient due to a hospitalization and then readmit the patient after hospital

discharge. However, we would not categorize post-acute care stays that occur during a previous 30-day period and within 14 days of a subsequent, contiguous 30-day period of care (that is, the admission date and from date for the subsequent 30-day period of care do not match) as institutional as we would expect the HHA to discharge the patient if the patient requires post-acute care in a different setting (for example, a SNF or IRF) and then readmit the patient, if necessary, after discharge from such setting. If the patient is discharged and then readmitted to home health, the admission date and from date on the 30-day claim will match and the claims

⁴¹ Medicare Payment Advisory Commission (MedPAC). “Home Health Care Services.” *Report to Congress: Medicare Payment Policy*. Washington, DC, March 2016. P. XX. Accessed on March 28,

2017 at <http://www.medpac.gov/docs/default-source/reports/chapter-8-home-health-care-services-march-2016-report-.pdf?sfvrsn=0>.

⁴² <https://oig.hhs.gov/oei/reports/oei-02-01-00070.pdf>; “Medicare Home Health Care Community Beneficiaries 2001”; HHSM–500–2010–00072C 12.

processing system will look for an acute or a post-acute care stay within 14 days of the home health admission date. This admission source designation process would be applicable to institutional stays paid by Medicare or any other payer. All other 30-day periods would be designated as community admissions.

We initially investigated maintaining two separate institutional categories, one for PAC and another for acute care settings, to identify any meaningful differences in resource use. However, we observed similar resource use in those cases where the patient was admitted from both PAC and acute care settings. Furthermore, in our analysis of the data from CY 2013, we found that the volume of home health cases with an admission from PAC settings across all 30-day periods of care was a low value at 736,112 cases (approximately 8 percent) out of a total of 8,539,996 cases as compared with cases admitted from acute settings at 1,376,567 cases (approximately 16 percent). The number of cases admitted from acute settings was approximately double the number

of cases admitted from PAC settings. Moreover, in the creation of case-mix groups that differentiated between community, acute, and PAC admission sources, there were some case-mix groups with a very low number of 30-day periods of care, which in turn can result in substantial variability in the average resource use from year- to- year. We were concerned that this variability could introduce unnecessary instability in the case-mix weights under the proposed HHGM. As such, we are proposing to group 30-day periods of care for patients admitted from acute care and PAC settings together as “institutional” admissions.

We also considered the employment of a “look-back” period for determining the admission source that was longer than 14 days and thus examined data for a longer 30-day “look-back” period to assess the resource utilization for patients admitted to home health from institutional and community settings; however, our findings indicated that there is only a slight difference in resource use, as well as volume of beneficiaries utilizing PAC or acute

services before home health between the two timeframes. Table 33 shows the distribution of 30-day periods and average resource utilization with admission source categories now defined by service use for beneficiaries in the 30 days prior instead of 14 days prior. In general, results are similar to those for the 14-day look-back period when compared to the 30-day “look-back” window. Average resource use under a 14-day “look-back” period for institutional entrants is at \$2,165.06 while the 30-day entrants show an average resource use of \$2,140.40. The same similarity holds true for community entrants, who show an average resource use of \$1,393.10 for the 14-day “look-back” period versus \$1,382.38 under the 30-day window. We note that the 30-day “look-back” period only produces a slightly higher proportion of institutional periods of care, at 2,315,557 periods as compared with the 14-day period value of 2,153,712, a difference of approximately 10 percent.

TABLE 33—AVERAGE RESOURCE USE BY ADMISSION SOURCE
[30 Day look-back]

Admission source	Average resource use	Number of 30-day periods	Percent of 30-day periods	Standard deviation of resource use	25th Percentile of resource use	Median resource use	75th Percentile of resource use
Institutional	\$2,140.40	2,315,557	26.79%	\$1,354.34	\$1,197.39	\$1,873.71	\$2,748.79
Community	1,382.38	6,326,550	73.21	1,202.14	567.05	1,049.66	1,823.04
Total	1,585.48	8,642,107	100.00	1,289.23	671.96	1,262.65	2,119.49

Source: CY2016 Medicare Home Health Claims Data (as of March 17, 2017).

We believe that a 14-day “look-back” period is more likely to be directly related to the patients’ need for home health care than a 30-day “look-back” period. This would also be more intuitive for HHAs, as the OASIS item M1000 specifically assesses whether a beneficiary was discharged from an institutional setting within the past 14 days. Thus, we ultimately are proposing to use the 14-day “look-back” period as we believe it will better categorize those beneficiaries with a relatively short transition between institutional care and home health care. Given that beneficiary admission source has previously been utilized for the purposes of Medicare home health payment, HHAs will be familiar with this concept. Moreover, the proposed 14-day “look-back” period simplifies the structure of the proposed model and limits burden on claims systems and related processing. Additionally, a “look-back” period of 14 days is consistent with section

1861(tt)(1) of the Act, which defines the term “post-institutional home health services”.

To differentiate between an institutional and community admission source, we would establish an evaluation process whereby the Medicare claims processing system would check for the presence of an acute/post-acute Medicare claim occurring within 14 days of the home health admission on an ongoing basis. In the past, HHAs stated that they had encountered challenges in terms of identifying the source of admission for home health beneficiaries, and we believe that an automated systems approach where Medicare systems evaluate for the presence of an institutional claim within the 14-day “look-back” window will serve to overcome this earlier challenge. Under this approach, the Medicare systems would only evaluate for whether an acute/post-acute Medicare claim

occurring within 14 days of the home health admission was processed by Medicare, not whether it was paid.

Moreover, we propose that newly-created occurrence codes would also be established that would allow HHAs to manually indicate on Medicare home health claims an institutional admission source prior to an acute/post-acute Medicare claim, if any, being processed by Medicare systems. We note that the use of these occurrence codes would not be limited to home health beneficiaries for whom the acute/post-acute claims were paid by Medicare. HHAs would also use the occurrence codes for beneficiaries with acute/post-acute care stays paid by other payers, such as the Veterans Administration. Although a home health claim with a non-Medicare institutional admission source can be categorized by the HHA as an institutional admission and paid accordingly, we may conduct medical review as discussed below. We expect

home health agencies would utilize discharge summaries from institutional providers to inform the usage of these occurrence codes. We note that these discharge documents should already be part of the beneficiary's home health medical record used to support the certification of patient eligibility as outlined in § 424.22(c).

If an occurrence code is submitted on the home health claim, the home health claim would be categorized as an institutional admission. However, if a home health claim is submitted without an institutional admission occurrence code, thereby categorizing it with a community admission source, and later an acute/post-acute Medicare claim for an institutional stay occurring within 14 days of the home health admission is submitted within the timely filing deadline and processed by the Medicare systems, the home health claim would be automatically adjusted and re-categorized as an institutional admission and appropriate payment modifications would be made. Our systems would adjust community-admitted home health claims on a claim-by-claim, flow basis if an acute/post-acute Medicare claim for an institutional stay occurring within 14 days of the home health admission is received. Given that our systems can only evaluate for the presence of a Medicare acute/post-acute claim, if there was a non-Medicare institutional stay occurring within 14 days of the home health admission but the HHA was not aware of such a stay, upon learning of the institutional stay, the HHA would be able to resubmit a home health claim that included an occurrence code, subject to the timely filing deadline, and payment adjustments would be made accordingly.

Conversely, if an occurrence code is submitted on the home health claim along with dates of the institutional stay, and an acute/post-acute Medicare claim for an institutional stay occurring within 14 days of the home health admission is not subsequently submitted within the timely filing

deadline and processed by the Medicare systems, or an acute/post-acute Medicare claim for an institutional stay occurring within 14 days of the home health admission was submitted but later denied for payment, we may conduct post-payment medical review of the home health claim to determine whether the admission was in fact preceded by an institutional stay occurring within 14 days of the home health admission. If upon medical review a determination is made that the admission was not from an institutional setting, we would take appropriate administrative action, including correcting any improper payments and potentially referring the provider to another CMS review contractor for further review or investigation. In summary, we believe that allowing HHAs to submit a claim with an institutional admission occurrence code for a beneficiary with either a Medicare or non-Medicare institutional admission source would enable HHAs to receive appropriate payment for the home health services, while also allowing us the opportunity and flexibility to verify the source of the admission and correct any improper payments as deemed appropriate.

For the purposes of a RAP, we would only adjust the final home health claim submitted for source of admission. For example, if a RAP for a community admission was submitted and paid, and then an acute/post-acute Medicare claim was submitted for that patient before the final home health claim was submitted, we would not adjust the RAP and would only adjust the final home health claim so that it reflected an institutional admission. Additionally, HHAs would only indicate admission source occurrence codes on the final claim and not on any RAPs submitted.

We invite public comments on the admission source component of the proposed HHGM payment system.

6. Proposed Clinical Groupings

a. Background

As discussed in section II.D of this proposed rule, the Home Health Study

Report to Congress found that the current payment system may encourage HHAs to select certain types of patients over others, as some clinical sub-groups within the current case mix system are associated with lower margins.⁴³ These sub-groups include patients with a higher severity of illness, including those receiving a greater level of skilled nursing care; for example, patients with wounds, with ostomies, or who are receiving total parenteral nutrition or mechanical ventilation. Additionally, the Medicare Payment Advisory Commission (MedPAC) has expressed concerns that the HH PPS disincentivizes care for patients needing skilled nursing visits, thereby limiting access of care to the most clinically vulnerable patient populations.⁴⁴

Although the clinical domain of the current case-mix system accounts for whether or not the patient has one or more certain clinical conditions, there could be improvements in clarity regarding patient needs to clearly explain resource use and cost. Given that payment should be predicated on resource use, providing additional clinical groups in the case-mix system and adjusting payment based on identified clinical characteristics and associated services, along with other patient variables, should better align payment with resource use. As such, under the HHGM, we propose grouping 30-day periods of care into six clinical groups designed to capture the most common types of care that HHAs provide. The proposed groups mirror how clinicians differentiate between patients as to what types of care they are receiving. To inform the development of the clinical groups, Abt Associates and CMS conducted an extensive review of diagnosis codes to identify the primary reasons for home health services under the Medicare home health benefit. The workgroup developed six clinical groups reflecting the reported principal diagnosis, clinical relevance, and coding guidelines and conventions, see Table 34.

TABLE 34—CLINICAL GROUPS USED IN THE HOME HEALTH GROUPINGS MODEL

Clinical groups	The primary reason for the home health encounter is to provide:
Musculoskeletal Rehabilitation	Therapy (physical, occupational or speech) for a musculoskeletal condition.
Neuro/Stroke Rehabilitation	Therapy (physical, occupational or speech) for a neurological condition or stroke.

⁴³ Report to Congress. Medicare Home Health Study: An Investigation on Access to Care and Payment for Vulnerable Patient Populations. Available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/>

HomeHealthPPS/Downloads/HH-Report-to-Congress.pdf.

⁴⁴ Report to the Congress: Medicare Payment Policy. (2015) Home health care services: Assessing

payment adequacy and updating payments. Ch.9 <http://www.medpac.gov/docs/default-source/reports/chapter-9-home-health-care-services-march-2015-report-.pdf?sfvrsn=0>.

TABLE 34—CLINICAL GROUPS USED IN THE HOME HEALTH GROUPINGS MODEL—Continued

Clinical groups	The primary reason for the home health encounter is to provide:
Wounds—Post-Op Wound Aftercare and Skin/Non-Surgical Wound Care.	Assessment, treatment & evaluation of a surgical wound(s); assessment, treatment & evaluation of non-surgical wounds, ulcers, burns, and other lesions.
Behavioral Health Care	Assessment, treatment & evaluation of psychiatric conditions.
Complex Nursing Interventions	Assessment, treatment & evaluation of complex medical & surgical conditions including IV, TPN, enteral nutrition, ventilator, and ostomies.
Medication Management, Teaching and Assessment (MMTA).	Assessment, evaluation, teaching, and medication management for a variety of medical and surgical conditions not classified in one of the above listed groups.

The 30-day periods of care were assigned to one of the six clinical groups based on the reported principal diagnosis. However, roughly 19 percent of 30-day periods could not be assigned to a clinical group based on principal diagnosis alone. Reasons for the inability to group 30-day periods based on primary diagnoses included codes that were too vague, meaning the code did not provide adequate information to support the need for home health services (for example, T14.90 Injury, unspecified); codes that would not be Medicare covered services in other settings (for example, dental codes); codes that would be unlikely to require skilled home health services (for

example, R68.89 Other general symptoms and signs); codes that indicate death as the outcome (for example, G93.82, Brain death); manifestation codes, where coding guidelines require an etiology code to be reported as a principal diagnosis (for example, I39 Endocarditis and heart valve disorders in diseases classified elsewhere); or code first, meaning the diagnosis is subject to sequencing conventions under ICD-10-CM, where the underlying condition must be sequenced first (for example, dementia in Parkinson's disease, in which Parkinson's disease must be sequenced first). In these instances, 30-day periods were considered “questionable

encounters” and secondary diagnosis codes were examined to group the 30-day period of care. An ICD-10-CM list with all of the codes that would assign 30-day periods into the six clinical groupings can be found on CMS's HHA Center Web page at <https://www.cms.gov/center/provider-Type/home-Health-Agency-HHA-Center.html>. More information on the analysis and development of the groupings can be found in the HHGM technical report, also available on the HHA Center Web page. Table 35 shows the distribution of episodes and associated resource use across the six clinical groups.

TABLE 35—FREQUENCY AND ASSOCIATED RESOURCE USE OF CLINICAL GROUPS

Clinical group	Average resource use	N	Percent	Standard deviation of resource use	25th Percentile of resource use	Median resource use	75th Percentile of resource use
Musculoskeletal Rehabilitation	\$1,713.10	1,430,813	16.56	\$1,149.61	\$1,495.09	\$878.95	\$2,276.98
Neuro/Stroke Rehabilitation	1,811.74	772,579	8.94	1,319.45	1,511.06	851.12	2,434.60
Wound	2,055.47	906,782	10.49	1,666.59	1,609.16	955.17	2,623.31
Behavioral Health	1,252.08	289,513	3.35	1,019.25	954.32	505.15	1,704.72
Complex Nursing Interventions	1,703.24	336,249	3.89	1,573.15	1,240.74	675.88	2,206.54
MMTA	1,437.37	4,906,171	56.77	1,200.35	1,105.63	589.92	1,936.81
Total	1,585.48	8,642,107	100.00	1,289.23	1,262.65	671.96	2,119.49

Table 35 illustrates the differences in average resource use between 30-day periods with similar care needs. Under the HHGM, we propose that each 30-day period would be assigned to a clinical group according to the primary reason the patient was receiving home health, which would be derived from the principal diagnosis code reported on the home health claims. If a 30-day period of care could not be grouped based on the home health reported principal diagnosis due to the reasons listed above, we propose that the claim for that 30-day period would remain a questionable encounter and be returned to the provider for more accurate or definitive coding. Upon publication of this proposed rule, we will post a complete list of ICD-10 codes and their

assigned clinical groupings on the CMS HHA Center Web page (<https://www.cms.gov/center/provider-Type/home-Health-Agency-HHA-Center.html>) to allow ample time for HHAs to understand those codes which would be considered a “questionable encounter.” We believe this will help to minimize any returned claims for more definitive coding. Each code should be reported to the level of certainty and specificity known for the home health admission. Under our proposal, secondary diagnosis codes would not be used to assign the clinical group, as the intent of the HHGM is to increase clarity by classifying the 30-day period based on the primary reason for home health services. Although the principal diagnosis code is the basis for the home

health period, secondary diagnosis codes would then be used to case-mix adjust the period further through additional elements of the model, such as the comorbidity adjustment. Using principal diagnoses as the core of the model would create a clinically intuitive payment system that more clearly identifies the types of patients that are treated in home health. Diagnosis codes would also provide clarity and transparency since they are clearly described and reported on claims and other care tools. Additionally, they would support medical necessity for services furnished, and provide information for establishing the home health plan of care. Ultimately, developing clinically similar groups based on the reported principal

diagnosis as part of the larger structure of the model would allow for more meaningful analysis of home health resource use, ensure that patients are receiving care commensurate with their level of need, and more accurately align payment with cost.

b. Musculoskeletal and Neuro/Stroke Rehabilitation

Rehabilitation is an integral part of recovery following an illness, injury, or surgical procedure, whether due to a neurological or a musculoskeletal condition. Given that different care goals and expected outcomes of neuro-rehabilitation and musculoskeletal rehabilitation affect resource use, the clinical groups in the HHGM would differentiate between the two. Patient characteristics between the two groups determine whether resources are directed towards preventing the loss of function or slowing the rate of loss of function; improvement or restoration of function; compensation for lost function; and maintenance of current function.⁴⁵ Musculoskeletal rehabilitation focuses on individuals with impairments or disabilities due to disease, disorders, or trauma to the muscles or bones, whereas neurological rehabilitation is designed for individuals with disease, trauma, or disorders of the nervous system.⁴⁶ Rehabilitation following a stroke, for instance, is primarily initiated early and intensively with the most recovery of function occurring within the first 3 months;⁴⁷ however, reacquiring the skills to perform ADLs may be an on-going process depending on the extent and area of injury. However, if improvement or recovery are not expected or achieved, the focus of therapy may shift to maintenance to prevent further decline. Therefore, the VA Clinical Practice Guidelines for Management of Stroke Rehabilitation “strongly recommend that rehabilitation therapy should start as early as possible, once medical stability is reached” and “recommend that the patient receive as much therapy as needed and tolerated to adapt, recover, and/or reestablish the

premorbid or optimal level of functional independence.”⁴⁸ Neuro-rehabilitation resource use can encompass evaluation and treatment of impairments in cognitive and spatial functioning, swallowing, communication, and psychological or emotional deficit; whereas musculoskeletal rehabilitation generally focuses on evaluation and treatment of the impaired muscle, bone, or joint. Musculoskeletal rehabilitation is more targeted toward proprioception, strength, imbalances, orthopedic surgeries, and abnormal functional movement patterns, and generally streamlines resources following a surgery or injury. Because of these clinical differences and associated resource use differences based on variables in length and intensity of rehabilitation, the HHGM would adjust payment between musculoskeletal and neuro/stroke rehabilitation accordingly.

c. Wounds

Wound care is provided in a variety of settings, including in the home. Advances in wound care treatments have increasingly allowed for a wide range of wound therapies to be provided in the home.⁴⁹ According to the article “Wound Care Outcomes and Associated Cost Among Patients Treated in US Outpatient Wound Centers: Data From the US Wound Registry,” a “rough population prevalence rate for chronic non-healing wounds in the United States is 2 percent of the general population,” with an estimated cost of caring for these wounds exceeding \$50 billion a year.⁵⁰ Non-healing, chronic wounds are often found in home health patients considering “prolonged and non-healing connective tissue injuries are often associated with common diseases, such as metabolic disorders, obesity, hypertension, arteriosclerosis, neuropathy, and diabetes mellitus,”⁵¹ which are among the top home health diagnoses.

Surgical wound care is essential at preventing post-operative complications such as surgical site infections (SSIs) and dehiscence. Research has shown that post-discharge SSIs occur in 3 to 5

percent of all surgical patients, and up to 33 percent of patients undergoing abdominal surgery, and that “more than half of patients who develop post-discharge SSIs are readmitted to the hospital, making SSIs the overall costliest healthcare-associated infection.”⁵² Home care management of burns requires a variety of resources as “burn patients are unique, representing the most severe model of trauma.”⁵³ The management of burn injury involves a multidisciplinary approach which may include nurses, occupational and physical therapists, dietitians, and psychosocial experts. Pressure ulcers are associated with an increased risk of morbidity and mortality and have a variety of intrinsic and external factors affecting their incidence and treatment. The incidence of pressure ulcers in home health is projected to rise due to the aging population, increasingly fragmented care, and nursing shortage.⁵⁴ Ultimately, wound care depends on a multitude of characteristics driving resource utilization. By highlighting them as a clinical group, the HHGM would recognize the variety of resources and skills that necessitate careful treatment and healing of different types of wounds, and more accurately ascribe resource use to payment.

d. Behavioral Health Care

The World Health Organization (WHO) defines health as “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.”⁵⁵ As such, behavioral and mental home health is an important clinical group of the HHGM. If all eligibility and coverage criteria are met according to § 409.42, then a patient may receive skilled nursing services for the assessment, treatment, and evaluation of psychiatric conditions. The Home Health Benefit Policy Manual states that “the evaluation, psychotherapy, and teaching needed by a patient suffering from a diagnosed psychiatric disorder that requires active treatment by a

⁴⁵ World Health Organization. (2011). Rehabilitation. World Report on Disability. Chapter 4. Retrieved from http://www.who.int/disabilities/world_report/2011/chapter4.pdf.

⁴⁶ Johns Hopkins Online Health Library. Neurological Rehabilitation. Retrieved from http://www.hopkinsmedicine.org/healthlibrary/conditions/adult/physical_medicine_and_rehabilitation/neurological_rehabilitation_85,P01163/.

⁴⁷ Stinear, C., Ackerley, S., Byblow, W. (2013) Rehabilitation is Initiated Early After Stroke, but Most Motor Rehabilitation Trials Are Not. Stroke. 2013; 44:2039–2045. <https://doi.org/10.1161/STROKEAHA.113.000968>.

⁴⁸ http://www.healthquality.va.gov/guidelines/Rehab/stroke/Mgmt_of_Stroke_Rehab_03151.pdf.

⁴⁹ Rhee, S., Valle, M., Wilson, L., Lazarus, G., Zenilman, J., Robinson, K. (2015). Negative pressure wound therapy technologies for chronic wound care in the home setting: A systematic review. Wound Repair and Regeneration. 23, 506–517.

⁵⁰ <http://www.woundsresearch.com/article/wound-care-outcomes-and-associated-cost-among-patients-treated-us-outpatient-wound-centers-d>.

⁵¹ Ackermann, P., Hart, D. Influence of Comorbidities: Neuropathy, Vasculopathy, and Diabetes on Healing Response Quality. (2013) Adv Wound Care (New Rochelle), 2(8): 410–421. doi: 10.1089/wound.2012.0437.

⁵² Sanger, P., Hartzler, A., Han, S., et al. (2014) Patient Perspectives on Post-Discharge Surgical Site Infections: Towards a Patient-Centered Mobile Health Solution. PLoS One. 2014; 9(12): e114016. Published online 2014 Dec 1. doi: 10.1371/journal.pone.0114016.

⁵³ Al-Mousawi, A. MD, Mecott-Rivera, G. MD, Jeschke, M. MD, Ph.D., et al. (2009). Burn Teams and Burn Centers: The Importance of a Comprehensive Team Approach to Burn Care: Clin Plast Surg. 2009 Oct; 36(4): 547–554; doi: 10.1016/j.cps.2009.05.015.

⁵⁴ Lyder, C., Ayello, Elizabeth. (2008). Pressure Ulcers: A Patient Safety Issue. Patient Safety and Quality: An Evidence-based Handbook for Nurses. Chapter 12.

⁵⁵ Constitution of WHO: principles: <http://www.who.int/about/mission/en/>.

psychiatrically trained nurse, and the costs of the psychiatric nurse's services may be covered as a skilled nursing service."⁵⁶ However, the psychiatric care must be furnished by an agency that does not primarily provide care and treatment of mental diseases. Older adults may be more susceptible to psychiatric and behavioral health issues due to limited mobility, bereavement, loss of ability to live independently, or drop in socioeconomic status due to retirement.⁵⁷ Although psychiatric and behavioral conditions have different signs, symptoms, and treatment options than physical illness, mental health can have major consequences on physical health. Behavioral health research suggests that "a model of care including solely hospital based provision (usually inpatient and outpatient care) will be insufficient to provide access for people facing barriers to care."⁵⁸ Additionally, the length of stay among Medicare beneficiaries who have been hospitalized for mental illness has declined over the last decade, with patients being discharged to home health rather than extending a hospitalization.⁵⁹ For these reasons, behavioral home health remains a crucial aspect of keeping beneficiaries out of the hospital. Distinguishing it as a clinical group delineates the resources associated with the unique care needs of these patients and would more accurately assign payment based on patient characteristics.

e. Complex Nursing Interventions

Understandably, the growing trend toward providing more healthcare services in the community shifts an increasing number of complex nursing interventions to home health. Providing complex nursing interventions in the home reflects a patient population with "more complex health care needs who require more intensive medical services coordinated across multiple providers, as well as a wide range of social supports to maintain health and

functioning."⁶⁰ Because of the range and intensity of services needed, these patients tend to generate high resource utilization and associated costs due to the need for a higher level of knowledge and expertise.⁶¹ Additionally, readmission rates can be high in this vulnerable population as patients adjust to their home with therapies generally administered in the hospital or post-acute environment.⁶²

For instance, the introduction of home mechanical ventilation is a technological advancement that not only keeps healthcare costs down but also allows patients, whose condition would otherwise necessitate an institutional environment, a maximum quality of life. For example, the results from one study found that long-term mechanical ventilation on average costs \$14,500 less per patient, per month when administered at home rather than in an acute or post-acute facility.⁶³ However, it does not come without challenges. Caregiver competency, evolving technology, changes in patient medical status, and safety of home environment can lead to higher home health resource utilization. Likewise, management of ostomies and vascular access devices (VADs) are associated with higher resource use in the home. The impact on patients living with VADs and ostomies is significant, with research identifying physical, psychological, and social effects.⁶⁴ Ostomy and VAD specific challenges or complications may occur initially and persist and change daily as patients learn to troubleshoot and manage life with an ostomy or VAD. Care often

requires resources aimed at education and support in addition to physical care. This can be made more challenging by the social and psychological effects that many new patients experience. Under the HHGM, ICD-10-CM codes on the home health claim that identify complex nursing interventions as the principal reason for home health would generate higher payment to account for these inherent challenges requiring additional resource utilization.

f. Medication Management, Teaching, and Assessment (MMTA)

Based on our analysis, the majority of 30-day periods of care in the HHGM would likely be classified under the MMTA clinical group. These 30-day periods would be characterized by codes that identify direct services related to the management and evaluation of the care plan, observation and assessment of the patient's condition, and training and/or education of a patient or family member that are not classified into one of the other clinical groups. The numerous and diverse conditions found in home health, and their associated medications and interventions, influence the principal diagnosis that would classify a 30-day period as under the MMTA clinical group.

Research on home health patient characteristics, home health nursing interventions, and outcomes of care show that there are four broad categories of interventions most frequently provided in the home:

- (1) Health teaching, guidance and counseling;
- (2) Treatments and procedures;
- (3) Case management; and,
- (4) Surveillance⁶⁵

Of these interventions, surveillance is the most frequently occurring intervention, closely followed by health teaching, guidance and counseling.⁶⁶ Specific patient problems most frequently identified in the home health setting are related to medication regimens, especially with polypharmacy, and health-related behaviors.⁶⁷ The majority of home health care patients routinely take more than five prescription drugs, and many likely deviate from their prescribed medication regimen.⁶⁸ This increases

⁶⁰ Rich, E., Lipson, D., Libersky, J., Parchman, M. (2012). Coordinating Care for Adults With Complex Care Needs in the Patient-Centered Medical Home: Challenges and Solutions WHITE PAPER, prepared by Mathematica Policy Research AHRQ Publication No. 12-0010 January 2012; <https://www.mathematica-mpr.com/our-publications-and-findings/publications/coordinating-care-for-adults-with-complex-care-needs-in-the-patientcentered-medical-home-challenges-and-solutions>.

⁶¹ Huisman-de Waal G., van Achterberg, T., Jansen, J., Wanten, G., Schoonhoven, L. (2011) High-tech home care: overview of professional care in patients on home parenteral nutrition and implications for nursing care: J Clin Nurs. 2011 Aug;20(15-16):2125-34. doi: 10.1111/j.1365-2702.2010.03682.x. Epub 2011 May 25.

⁶² Vallab, H., Konrad, D., DeChicco, R., et al (2016). Thirty-Day Readmission Rate Is High for Hospitalized Patients Discharged With Home Parenteral Nutrition or Intravenous Fluids, JPEN J Parenter Enteral Nutr. 2016 Aug 18. doi: 0148607116664785.

⁶³ King, A. Long-Term Home Mechanical Ventilation in the United States. (2012). Respiratory Care June 2012, 57 (6) 921-932; doi: <https://doi.org/10.4187/respcare.01741>.

⁶⁴ Grant, M. RN, DNS, FAAN, McCorkle, R. Ph.D., FAAN, Hornbrook, M. Ph.D., et al. (2013). Development of a Chronic Care Ostomy Self-Management Program. J Cancer Educ. 2013 Mar; 28(1): 70-78. doi: 10.1007/s13187-012-0433-1.

⁵⁶ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c07.pdf>.

⁵⁷ World Health Organization: Mental Health and Older Adults. Retrieved from <http://www.who.int/mediacentre/factsheets/fs381/en/>.

⁵⁸ Thornicroft, G., Deb, T., Henderson, C. (2016) Community mental health care worldwide: current status and further developments. World Psychiatry, 15(3): 276-286. Published online 2016 Sep 22. doi: 10.1002/wps.20349.

⁵⁹ Banta, J., Belk, I., Newton, K., Sherzai, A. (2010) Inpatient Charges and Mental Illness: Findings from the Inpatient Sample 1999-2007. Clinicoecon Outcomes Res2010; 2: 149-158.

Published online 2010 Oct 11. doi: 10.2147/CEOR.S7560.

⁶⁵ Martin, K., Scheet, N., Stegman, M.R. (1993). Home Health Clients: Characteristics, Outcomes of Care, and Nursing Interventions. American Journal of Public Health. 83(12), 1730-1734.

⁶⁶ Ibid.

⁶⁷ Ibid.

⁶⁸ Ellenbecker, C., Samia, L., Cushman, M., Alster, K. (2008). Patient Safety and Quality in Home Health Care. Patient Safety and Quality: An Evidence-based Handbook for Nurses. Chapter 13.

the potential for medication errors or adverse effects in home health, highlighting the substantial need for education and medication management regardless of whether the patient needs wound care, rehabilitation, or complex nursing interventions.

Additionally, patients with comorbidities tend to be high users of home health,⁶⁹ making education and assessment of disease diagnosis, medication interactions, lifestyle changes, and avoidance of adverse events a considerable portion of home health care. In an elderly patient population, the number of chronic conditions increases with age. Medications used to treat or prevent blood clots (anticoagulants), diabetes (insulin), and pain (opioid analgesics) are some of the most commonly implicated drugs in emergency room visits and emergent hospitalizations for adverse drug events in older adults.⁷⁰ These adverse events can potentially be reduced by improving dosing and monitoring of these drugs in high risk populations and settings like older adults in home health programs.⁷¹ Anticoagulants are challenging to manage in home health settings and have been identified as targets for improvements in monitoring and care coordination by HHS. Also, as the number of medications being taken increases, so does the risk of adverse drug reactions, and the risk of drug reaction related emergency room visits and hospital admissions, especially in patients who are in poor health.⁷² Elderly patients are especially at risk for adverse drug reactions as the organs that metabolize drugs have reduced functional ability which can lead to increased toxicity.⁷³ Similarly, roughly 31 percent of younger Medicare beneficiaries with disabilities report having five or more chronic conditions.⁷⁴ Polypharmacy can lead to reduced compliance with medication

regimens, thus putting the patient at risk for adverse events resulting from poorly managed conditions. In the home healthcare setting, management of polypharmacy is a primary focus of nursing interventions.⁷⁵ These interventions include assessment of the patient's chronic conditions and medications used to treat those conditions; assessment of the patient's understanding of and compliance with his or her medication regimen; and teaching and reinforcing treatment and medication regimens. The medication review by the home health nurse can help reduce duplicate medications, medications that are contraindicated for older adults, and provide ways to ensure patients are being appropriately monitored and understand why they are taking the medications as well as how to take them correctly.⁷⁶

Other studies show that primary functions of home health care skilled nursing interventions include providing disease-specific and general health information; helping patients to practice and refine disease management skills; assessing efficacy of treatment; and, advocating for any needed changes to established treatment and drug regimens.⁷⁷ The interventions encompassed under the MMTA clinical group are shown extensively in research literature to be the most prevalent services provided by home health clinicians. Analysis of home health episodes for the HHGM suggests that the MMTA services would be the most frequent home health service being provided to Medicare home health beneficiaries.

We believe that the proposed clinical groupings add a needed level of clarity in identifying and meeting the needs of home health patients; particularly the patient populations addressed in the Home Health Study Report to Congress as outlined in section II.D. of this proposed rule. Recognizing that all 30-day periods of home health care cannot be defined by the principal diagnosis alone, the clinical groupings would only be one step in the case-mix adjustment under the HHGM. We invite comments on the proposed clinical groups, which are designed to capture the most common types of care that HHAs provide.

7. Functional Levels and Corresponding OASIS Items

Research has shown a relationship exists between functional status, rates of hospital readmission, and the overall costs of health care services.⁷⁸ Functional status is defined in a number of ways, but generally, functional status reflects an individual's ability to carry out activities of daily living (ADLs) and to participate in various life situations and in society.⁷⁹ The assessment of functional status is often called "the sixth vital sign", which reflects its clinical relevance in the plan of care. CMS requires the collection of data on functional status in home health through a standardized assessment instrument: The Outcome and Assessment Information Set (OASIS).⁸⁰ Under the current HH PPS, functional status is assessed through the following OASIS items:

- M1810: Dressing Upper Body.
- M1820: Dressing Lower Body.
- M1830: Bathing.
- M1840: Toileting.
- M1850: Transferring.
- M1860: Ambulation/Locomotion.

For each of these OASIS items, the clinician or therapist conducting the assessment selects a numbered checkbox that best describes the patient's functional status in terms of ability to perform certain tasks. These numbered checkboxes typically range from zero, meaning independent with the task or no functional deficits, to higher numbers, meaning decreasing independence and/or increasing deficits. Responses to these OASIS items result in "points" to calculate an overall functional score which conveys the functional status of the patient. This means that patients with a higher functional score (that is, reduced functional status) have, on average, higher resource use compared to patients with a lower functional score (that is, higher functional status). As such, the functional status of the patient is a useful case-mix adjuster. Including functional status in the case-mix adjustment methodology allows for higher payment for those patients with

⁶⁹ Center for Healthcare and Transformation. (2010). Health Care Cost drivers: Chronic Disease, Comorbidity and Health Risk Factors in the U.S. and Michigan. Center for Healthcare and Transformation.

⁷⁰ Budnitz DS, Lovegrove MC, Shehab N, Richards CL. Emergency hospitalizations for adverse drug events among older Americans. *N Engl J Med* 2011;365:2002–2012.

⁷¹ U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. (2014). National Action Plan for Adverse Drug Event Prevention. Washington, DC.

⁷² Alpert, P., Gatlin, T. (2015). Polypharmacy in Older Adults. *Homehealth Care Now*. 33(10), 524–529.

⁷³ Ibid.

⁷⁴ Cubanski, J., Neuman, T., Damico, A. (2010, August) *Medicare's Role for People Under Age 65 with Disabilities*. Retrieved from <http://kff.org/medicare/issue-brief/medicare-role-for-people-under-age-65-with-disabilities/>.

⁷⁵ Ibid.

⁷⁶ Ibid.

⁷⁷ Liebel, D., Powers, B.A., Friedman, B., Watson, N. (2011). Barriers and Facilitators to Optimize Function and Prevent Disability Worsening: A Content Analysis of a Nurse Home Intervention. *Journal of Advanced Nursing*. 68(1), 80–93.

⁷⁸ Burke, R. MD, MS, Whitfield, E. Ph.D., Hittle, D. Ph.D., Min, S. Ph.D., Levy, C. MD, Ph.D., Prochazka, A. MD, MS, Coleman, E. MD, MPH, Schwartz, R. MD, Ginde, A. (2016). "Hospital Readmission From Post-Acute Care Facilities: Risk Factors, Timing, and Outcomes". *The Journal of Post-Acute Care and Long Term Care Medicine*. (17), 249–255.

⁷⁹ Clauser, S. Ph.D., and Arlene S. Bierman, M.D., M.S. (2003). "Significance of Functional Status Data for Payment and Quality". *Health Care Financing Review*. 24(3), 1–12.

⁸⁰ Bierman, A. (2001). "Functional Status: The Sixth Vital Sign". *Journal of Internal Medicine*. 16(11), 785–786.

higher service needs. As functional status is commonly used for risk adjustment in various payment systems, including in the current HH PPS, the proposed HHGM would also adjust payments to account for differences in resource use associated with functional status.

During the development of the HHGM, each OASIS-C item was evaluated using clinical review and analytical methods. Because the current case-mix adjustment methodology already utilizes OASIS items associated with functional status to adjust the home health payment, utilizing these OASIS items for inclusion in the HHGM was a primary focus. All OASIS items, including items not used in the current case-mix adjustment methodology, were evaluated for potential inclusion in the HHGM. OASIS items were eliminated for inclusion based on statistical factors (for example, the relationship of the item with resource use), clinical factors (for example, clinical appropriateness of using the item for payment purposes) and incentive factors (for example, potential for unintended consequences such as overutilization solely for increased reimbursement).

We presented our analysis of the OASIS items to a clinical workgroup that included physicians, nurses, and therapists with substantial home health clinical expertise, to obtain input regarding which OASIS items to include in the HHGM. Based on the clinical workgroup feedback and additional analyses by the research team, the following decisions were made regarding the narrowed list of OASIS items being considered for a functional status payment adjustment under the HHGM:⁸¹

- *M066, M0110: Age, Episode timing*—Both age and episode timing were determined to be appropriate for the HHGM, but both items can be accurately obtained directly from the home health claims data, rather than the OASIS. As such, responses on these OASIS items would not be used for this functional status adjustment under the HHGM.

- *M1018, M1030: Selected prior conditions and types of therapies a patient receives*—These OASIS items would not be used for functional status adjustment in the HHGM because the clinical groups, specifically Complex Nursing Interventions, (described in section III.E.6. of this proposed rule) account for most of the conditions described in these OASIS items (for example, IV therapy, TPN) so using

these OASIS items would be duplicative.

- *M1200: Vision*—The clinical workgroup believed this OASIS item to be clinically significant. However, while this item is used in the current HH PPS, there are no longer “points” associated with this item for the clinical domain because there is no additional resource use related to this item beyond the average across all periods of care. Additionally, analysis of this vision impairment OASIS item showed decreased resource use in the HHGM and; therefore, was determined to have a counterintuitive relationship. As a result, this OASIS item would not be used for functional status adjustment in the HHGM. Analysis of this item is found in the “Overview of the Home Health Groupings Model” technical report found on the HHA Center Web page.⁸²

- *M1220, M1230: Understanding of verbal content, speech and oral*—These items were determined to be subjective in nature and may not provide information that is an accurate reflection of the patient’s cognitive status. As with other OASIS items in this analysis, these items showed that there was decreased resource costs associated with worsening status. As a result, these OASIS items would not be used for functional status adjustment in the HHGM.

- *M1242: Pain*—While this item is used in the current HH PPS, this is shown to have only a minimal relationship with resource use in the current payment model. Although the clinical workgroup believed this item to be clinically significant, CMS clinicians agreed this one item alone may not be robust enough to fully capture the pain presentation of the patient and its impact on resource utilization. Therefore, this OASIS item would not be used for functional status adjustment in the HHGM.

- *M1302, M1308, M1320, M1322, M1324, M1332, M1334, and M1340: Ulcers and wounds*—These OASIS items would not be used for functional status adjustment in the HHGM because the Wound clinical group (described in section III.E.6 of this proposed rule) already adjusts the period payment for these conditions and using these OASIS items would be duplicative.

- *M1400: Shortness of breath*—Although the clinical workgroup believed this item to be clinically significant, this OASIS item would not

be used for functional status adjustment in the HHGM because the analysis showed decreased resource costs with worsening dyspnea which appears to be clinically counterintuitive.⁸³

- *M1700—M1750: Cognitive items*—These items were initially determined to be clinically appropriate for inclusion in the HHGM but were later removed due to analysis that showed a counterintuitive relationship, meaning costs decreased as cognitive status worsened. This negative relationship with resource use was consistent with most of the OASIS cognitive items. This analysis is discussed more in depth in this section below and the full analysis of all of the cognitive items is found in the technical report.

- *M1800—M1890: Functional items*—These OASIS items include both ADLs and Instrumental Activities of Daily Living (IADLs). ADLs are routine activities that people tend to do every day without needing assistance. There are six basic ADLs: Eating, bathing, dressing, toileting, transferring (walking) and continence. IADLs are activities related to independent living and include preparing meals, managing money, shopping for groceries or personal items, performing light or heavy housework, doing laundry, and using a telephone. While most of these items were determined to be clinically appropriate for inclusion in the HHGM, M1870—M1890 (IADLs) would not be used for functional status adjustment in the HHGM due to responses having a negative relationship with resource use (for example, worsening status in performing IADLs was associated with decreased resource use).

- *M2030: Management of injectable medications*—This OASIS item would not be used for functional status adjustment in the HHGM because most of the responses associated with this item reflected less resource use when the patient increasingly had issues with preparing and taking injectable medications. We believe that clinically counterintuitive relationships resulting from responses to OASIS items, where the expectation would be to see increased resource costs associated with decreased function or ability, should not be included in the case mix adjustment.

In addition to the OASIS items listed above, the clinical workgroup also discussed M2100 (types and sources of assistance—specifically non-HHA caregiver assistance). Workgroup members agreed that the availability of non-agency caregiver assistance can be an important determinant of home health care needs. Caregiver availability

⁸¹ Version OASIS C items were used for this initial analysis.

⁸² “Overview of the Home Health Groupings Model” technical report, Appendix Exhibit A7–1 on the HHA Center Web page (<https://www.cms.gov/center/provider-type/home-health-agency-hha-center.html>).

⁸³ Ibid.

and assistance was a focus in the Report to Congress “Medicare Home Health Study: An Investigation on Access to Care and Payment for Vulnerable Patient Populations”. Vulnerable patient populations examined in this study included those patients with minimal or no caregiver support. Results from this study revealed that HHAs and physicians stated that family or caregiver issues are an important contributing factor in the inability to admit or place patients in home health.⁸⁴ However, the survey results suggest that much of the variation in access to Medicare home health services is associated with social and personal conditions, and therefore, CMS’ ability to improve access for certain vulnerable patient populations through payment policy alone may be limited.⁸⁵ OASIS–C item M2100 identifies the ability and willingness of the caregiver(s) (other than home health agency staff) to provide categories of assistance needed by the patient, including ADL/IADL assistance, medication administration, and management of equipment. This particular OASIS item is multi-faceted, meaning this item requires one of six responses for seven different types of caregiver assistance. Because the responses to this item generally are not based on direct observation by the clinician conducting the assessment, this presents a limitation for use in a case mix adjustment as the accuracy of the responses cannot be easily validated. Patients or caregivers may overestimate or underestimate their ability or willingness to assist in the patient’s care. Analysis of the resource use associated with this item showed ambiguous results where the same response (“assistance needed, but no caregiver(s) available”) would be associated with increased resource costs for certain types of assistance but decreased resource costs for other types of assistance. We believe this is clinically counterintuitive as it would be expected that if a need for caregiver assistance exists but there are no available caregivers, then the result would be an increased need for resources for all of the types of caregiver assistance listed on this OASIS item. Analysis of OASIS–C item M2110, frequency of ADL/IADL assistance, which identifies the frequency of assistance provided by non-agency

caregiver(s), also showed a counterintuitive and contradicting relationship with M2100. Therefore, these OASIS items would not be included as part of the functional status payment adjustment under the HHGM.

During the analysis of functional case mix adjustment under the HHGM, a review of the literature revealed growing evidence suggesting that cognitive dysfunction is an important risk factor in the development of functional disability and loss of independence.⁸⁶ The research team analyzed the responses to the OASIS items associated with cognitive status, but found there was decreased resource use associated with worsening cognitive status. We decided to further evaluate OASIS cognitive items (M1700–1750) in addition to functional items (M1800–1860), as well as other possible OASIS items that may contribute to overall function status. The following OASIS items were determined to be indicators of cognitive and functional status that potentially could be used as case mix adjusters:

- M066: Age.
- M1032: Risk of Hospitalization.
- M1220: Understanding of Verbal Content.
- M1230: Speech and Oral (Verbal) Expression of Language.
- M1700: Cognitive functioning.
- M1710: Confusion indicator.
- M1720: Anxiety indicator.
- M1740: Cognitive, behavioral, and psychiatric symptoms.
- M1745: Frequency of disruptive behavior symptoms.
- M1750: Receipt of psychiatric nursing services.
- M1800: Grooming.
- M1810: Current ability to dress upper body safely.
- M1820: Current ability to dress lower body safely.
- M1830: Bathing.
- M1840: Toilet transferring.
- M1845: Toilet hygiene.
- M1850: Transferring.
- M1860: Ambulation/locomotion.

One difficulty in using certain OASIS items (for example, M1700) to examine relationships with resource use is that they are only questioned on the Start of Care and Resumption of Care assessments, and not on follow-up assessments. Therefore, for this analysis, as outlined in the technical report, we looked back for the most recent period in the same sequence of periods that was linked to a Start of Care or

Resumption of Care assessment, and carried forward the information from that assessment to the subsequent periods of care linked to follow-up (recertification) assessments. Analysis of these items, including looking at interactions between certain items, continued to show decreased resource use associated with worsening severity. The research team believed that clinically counterintuitive relationships to resource use may have the unintended consequence of discouraging HHAs to provide the appropriate amount of care to the patients who are clinically complex and need home health services the most.

For several of the OASIS items listed above, particularly the functional items, worsening status is associated with higher resource use, indicating that these items may be useful as adjusters to construct case-mix weights for the HHGM. However, several responses within other individual OASIS items had very similar average resource use. Due to the lack of variation in resource use across certain responses and because certain responses were infrequently chosen, some responses were combined into larger response categories to better capture the relationship between worsening status and resource use. Responses on these OASIS items were combined using the following methodology:

- Responses that corresponded to a small number of periods were combined with responses that corresponded to a larger number of periods and;
- Responses that had similar average resource use were combined together.

The resulting combinations of responses for these OASIS items are found at Exhibit 7–2 in the HHGM technical report.⁸⁷

After making these combinations, the newly combined OASIS items and resource use were analyzed again to determine if those OASIS items could be used to help case-mix adjust periods within the HHGM. Results showed that decreasing functional status, increasing age, and increasing risk of hospitalization tended to be associated with higher resource use, while worsening cognitive status tended to be associated with lower resource use. The relationship between worsening cognitive status but lower resource use is counterintuitive to existing research regarding cognitive status and health

⁸⁴ Report to Congress Medicare Home Health Study: An Investigation on Access to Care and Payment for Vulnerable Patient Populations. Available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Downloads/HH-Report-to-Congress.pdf>.

⁸⁵ Ibid.

⁸⁶ Njegovan, V., Man-Song-Hing, M., Mitchell, S., Molnar, F. (2001). “The Hierarchy of Functional Loss Associated with Cognitive Decline in Older Persons”. *Journal of Gerontology*. 56A(10), M638–643.

⁸⁷ <https://www.cms.gov/center/provider-type/home-health-agency-hha-center.html?redirect=/center/hha.asp>; <https://downloads.cms.gov/files/hhgm%20technical%20report%20120516%20sxf.pdf>.

care costs.⁸⁸ To further explore the relationship between the functional and cognitive OASIS items and resource use, additional analyses were conducted where the coefficients (that is, resource costs) associated with the functional and cognitive items were converted into a table of points to calculate the functional score for home health periods of care. However, even after controlling for each OASIS variable (as well as other components of the HHGM), the general trends between the cognitive and functional items from the other analyses remained the same. That is, worsening cognitive status was generally associated with less resource use; worsening functional status was generally associated with increased resource use; increased risk of hospitalization was associated with increased resource use; and age was not associated with either increased or decreased resource use. The summary statistics of these analyses are found at Exhibit 7–3 of the technical report, “Overview of the Home Health Groupings Model”.⁸⁹ Therefore, we decided not to include those OASIS items with these types of inverse relationships to resource costs as part of the adjustment to the HHGM period payment. However, given the research support and clinical input from home

health clinicians, we will continue to analyze the inclusion of cognitive items into the HHGM case mix adjustment. The analyses of the complete list of all OASIS items analyzed can be found in the Appendix Exhibits A7–1 and A7–2 of the technical report mentioned above.

On the basis of input from the clinical workgroup and these analytic results, all cognitive items, functional items with a negative relationship with resource use, and age were removed and the model was re-estimated. Each OASIS item included in the final model has a positive relationship with resource use, meaning as functional status declines (as measured by a higher response category), periods have more resource use on average. Additionally, periods with a higher risk of hospitalization (meaning four or more items checked on M1033) are associated with higher resource use compared with periods with a lower risk of hospitalization. This indicates that these items could be used to help risk adjust a period’s payment and help determine case-mix weights for the HHGM. As such, we are proposing that the following OASIS items be included as part of the functional payment adjustment under the proposed HHGM:

- M1800: Grooming.
- M1810: Current Ability to Dress Upper Body.

- M1820: Current Ability to Dress Lower Body.
- M1830: Bathing.
- M1840: Toilet Transferring.
- M1850: Transferring.
- M1860: Ambulation/Locomotion.
- M1032 (M1033 in OASIS–C1): Risk of Hospitalization.⁹⁰

While the original analyses of these OASIS functional items were conducted using CY 2013 data from the OASIS–C version (as presented in the technical report), the updated analyses for CY 2016 reported in Tables 36, 37, and 38 are based on data obtained from OASIS C–1. While the OASIS item number for “Risk of Hospitalization” changed from M1032 (in OASIS C) to M1033 (in OASIS C–1), the remaining OASIS items (and item numbers) used for this functional adjustment analysis are the same. As discussed earlier in this section, to facilitate the interpretation of this analysis of the functional items used to construct the case mix weights, the results of this analysis were converted into a table of points that can be used to calculate the functional score for a home health period. Table 36 shows the points for 2013 and 2016 for those items associated with increased resource use using a reduced set of OASIS C–1 items:

TABLE 36—OASIS POINTS TABLE FOR THOSE ITEMS ASSOCIATED WITH INCREASED RESOURCE USE USING A REDUCED SET OF OASIS ITEMS, CY 2013 AND CY 2016

Variable	Response category	Points (2013)	Points (2016)	Percent of periods in 2013 with this response category (%)	Percent of periods in 2016 with this response category (%)
M1800: Grooming	1	3	4	41.5	51.9
M1810: Current Ability to Dress Upper Body	1	4	6	46.6	55.6
M1820: Current Ability to Dress Lower Body	1	7	6	52.1	57.5
	2	10	12	16.4	19.6
M1830: Bathing	1	6	4	24.4	20.3
	2	17	14	46.1	51.6
	3	25	22	19.1	21.9
M1840: Toilet Transferring	1	4	5	20.3	28.2
M1850: Transferring	1	7	4	61.6	47.7
	2	13	9	29.2	48.0
M1860: Ambulation/Locomotion	1	13	12	37.7	29.0
	2	17	15	33.0	47.8
	3	27	27	12.7	14.2
M1032 (M1033 for OASIS C–1): Risk of Hospitalization	4 or more items checked	12	11	12.6	16.3

⁸⁸ P.P. Pandharipande, T.D. Girard, J.C. Jackson, A. Morandi, J.L. Thompson, B.T. Pun, N.E. Brummel, C.G. Hughes, E.E. Vasilevskis, A.K. Shintani, K.G. Moons, S.K. Geevarghese, A. Canonico, R.O. Hopkins, G.R. Bernard, R.S. Dittus, and E.W. Ely. (2013). “Long-Term Cognitive Impairment after Critical Illness”. *The New England Journal of Medicine*. 369(14), 1306–14.

⁸⁹ Abt Associates. “Overview of the Home Health Groupings Model.” *Medicare Home Health Prospective Payment System: Case-Mix Methodology Refinements*. Cambridge, MA, November 18, 2016. Accessed on April 27, 2017 at <https://www.cms.gov/center/provider-type/home-health-agency-hha-center.html?redirect=/center/hha.asp>; <https://downloads.cms.gov/files/>

hhgm%20technical%20report%20120516%20sxf.pdf.

⁹⁰ In Version OASIS C–1, two responses were excluded: “currently reports exhaustion” and “other risks not listed in 1–8”.

Similar to the current case-mix adjustment methodology, the points generated in Table 36 were then used to create a functional score for each home health period of care in the HHGM. That is, a home health period of care receives points based on each of the responses associated with the OASIS items listed above. The sum of all of these points results in a functional score which is used in the HHGM to group home health periods into a functional level. As part of the HHGM case-mix adjustment, we are proposing to assign

points for each of the responses to the proposed OASIS functional items and to sum up the points to create a functional score for the period of care. Whereas the results presented in the technical report showed that the number of functional levels varied by clinical group, continued analysis ultimately established three functional levels for each of the clinical groups—low, medium and high, with approximately one third of home health periods from each of the clinical groups within each level. This means home health periods

in the low level have responses for the above OASIS items that are associated with the lowest resource use on average. Home health periods in the high level have responses on the above OASIS items that are associated with the highest resource use on average. We are proposing to use the three functional levels of low, medium, and high, based on the CY 2016 data for each of the clinical groups. Table 37 shows the functional thresholds for each functional level by clinical group for CYs 2013 and 2016.

TABLE 37—THRESHOLDS FOR FUNCTIONAL LEVELS BY CLINICAL GROUP, CY 2013 AND CY 2016

Clinical group	Level	Points (2013 data)	Points (2016 data)
MMTA	Low	0–36	0–36
	Medium	37–55	37–54
	High	56+	55+
Behavioral Health	Low	0–30	0–38
	Medium	31–55	39–57
	High	56+	58+
Complex Nursing Interventions	Low	0–33	0–36
	Medium	34–60	37–59
	High	61+	60+
Musculoskeletal Rehabilitation	Low	0–37	0–39
	Medium	38–55	40–55
	High	56+	56+
Neuro Rehabilitation	Low	0–48	0–49
	Medium	49–67	50–66
	High	68+	67+
Wound	Low	0–41	0–42
	Medium	42–65	43–65
	High	66+	66+

Table 38 shows the average resource use by clinical group and functional level for CY 2016:

TABLE 38—AVERAGE RESOURCE USE BY CLINICAL GROUP AND FUNCTIONAL LEVEL, CY 2016

	Mean resource use	Frequency of periods	Percent of periods	Standard deviation of resource use	25th Percentile of resource use	Median resource use	75th Percentile of resource use
MMTA—Low	\$1,216.76	1,683,279	19.48	\$1,091.11	\$880.56	\$507.63	\$1,589.76
MMTA—Medium	1,466.19	1,594,451	18.45	1,182.78	1,163.49	617.07	1,979.71
MMTA—High	1,637.21	1,628,441	18.84	1,284.34	1,334.00	695.10	2,216.12
Behavioral Health—Low	963.97	100,572	1.16	847.72	679.14	407.74	1,255.47
Behavioral Health—Medium	1,308.10	94,030	1.09	1,018.11	1,040.79	543.96	1,780.03
Behavioral Health—High	1,501.87	94,911	1.10	1,107.73	1,237.97	662.86	2,047.39
Complex—Low	1,425.30	120,528	1.39	1,356.53	1,019.77	582.12	1,795.04
Complex—Medium	1,797.33	106,056	1.23	1,593.76	1,354.89	739.39	2,340.46
Complex—High	1,917.72	109,665	1.27	1,723.31	1,430.70	756.59	2,536.16
MS Rehab—Low	1,519.02	478,059	5.53	1,048.29	1,298.20	753.88	2,025.52
MS Rehab—Medium	1,730.99	480,676	5.56	1,121.66	1,534.42	921.87	2,296.70
MS Rehab—High	1,891.42	472,078	5.46	1,241.57	1,671.24	1,004.59	2,501.81
Neuro—Low	1,594.59	283,573	3.28	1,169.30	1,327.08	739.60	2,137.34
Neuro—Medium	1,847.36	233,398	2.70	1,271.54	1,581.08	914.70	2,487.14
Neuro—High	2,020.14	255,608	2.96	1,473.75	1,682.68	947.61	2,715.74
Wound—Low	1,860.42	305,556	3.54	1,550.96	1,436.36	861.98	2,345.97
Wound—Medium	2,052.45	303,435	3.51	1,603.05	1,646.76	980.27	2,634.01
Wound—High	2,258.66	297,791	3.45	1,814.01	1,771.12	1,043.72	2,897.54
Total	1,585.48	8,642,107	100.00	1,289.23	1,262.65	671.96	2,119.49

Like the annual recalibration of the case-mix weights under the current HH PPS, we expect that annual recalibrations would also be made to the HHGM case-mix weights. If the HHGM is finalized, we will continue to analyze all of the components of the case-mix adjustment, including adjustment for functional status, and would make refinements as necessary to ensure that payment for home health periods are in alignment with costs. We invite comments on the proposed OASIS items and the associated points and thresholds used to group patients into three functional levels under the HHGM, as outlined above.

8. Comorbidity Adjustment

The HHGM groups home health periods based on the primary reason for home health care (principal diagnosis), functional level, admission source, and timing. To further account for differences in resource use based on patient characteristics in the development of the HHGM, we analyzed the presence of comorbidities as another factor that could impact resource utilization and costs. We conducted a comprehensive literature review examining published, peer-reviewed research regarding the relationship between comorbidity and resource use.⁹¹ This review also included findings on those conditions that impact health care resource utilization. Based on this review and findings, we propose a comorbidity adjustment to account for higher costs associated with comorbidities.

A comorbidity is most often defined as two or more coexisting medical conditions or disease processes that are in addition to an initial diagnosis.⁹² Typically, a comorbidity is a condition(s) in which there is no direct correlation in the treatment of the principal diagnosis, but the presence of that condition(s) may impact the home health plan of care in terms of resource utilization and costs. With aging, the presence of comorbidity increases markedly because the frequency of individual conditions arises with age. While the elderly are far more likely to have multiple comorbidities, comorbidities also are prevalent in Medicare beneficiaries under the age of 65 who have intellectual and physical disabilities.⁹³ Research has repeatedly

shown that comorbidity is associated with high health care utilization and expenditures.⁹⁴ Additionally, comorbidity is tied to worse health outcomes and the need for more complex treatment and disease management, which in turn results in higher health care costs.⁹⁵ Patients with comorbidities tend to be high users of home health visits and overall Medicare spending increases with the number of chronic conditions.⁹⁶

In the home health setting, information regarding the patient's health conditions for which home health services are provided are assessed and documented by skilled clinicians on the OASIS. These conditions would include secondary diagnoses in addition to the principal diagnosis supporting the need for home health services. As such, exploratory analyses for the HHGM determined that secondary diagnoses (that is, comorbidities) provide additional information that can predict resource use even after controlling for the period's clinical group. We examined multiple approaches for a comorbidity adjustment in the HHGM and the analyses on these approaches is found in the "Overview of the Home Health Groupings Model" technical report found on the HHA Center Web page. Based on the results of these analyses, we moved towards the development of a home health specific comorbidity list for the HHGM comorbidity adjustment.

For the analysis of a comorbidity adjustment in the HHGM, some diagnosis exclusions were made. Under the HHGM, certain reported principal diagnosis codes, including some ICD-10-CM "R-codes" (R00-R99) which identify symptoms and abnormal clinical findings, would be considered a "questionable encounter", meaning these codes may be too vague to group the home health period, subject to sequencing or other ICD-10-CM coding conventions, not a Medicare-covered diagnosis, or a condition unlikely to require home health services. For these "questionable encounters", more

information was needed to assign the period to a clinical group. This meant, for analysis purposes only, we looked at the secondary diagnoses to assign the home health period to one of the six clinical groups. As such, those periods with a principal diagnosis that was determined to be a "questionable encounter" code were excluded from our comorbidity adjustment analysis. However, if the HHGM is finalized, we are proposing that claims submitted with principal reported diagnosis codes that are considered "questionable encounters" would be returned to the provider for more definitive coding. Once the claim is resubmitted without a principal diagnosis that is considered a "questionable encounter", the home health period would be grouped into one of the six clinical groups. The secondary diagnoses on those resubmitted claims would then be eligible for the comorbidity adjustment.

Another exclusion from this comorbidity analysis included those secondary diagnoses that had the same three character ICD-10-CM code as the diagnosis used to assign a case to a particular clinical group (that is, musculoskeletal rehab, neuro/stroke rehab, wounds, behavioral health, complex nursing interventions, and MMTA). An additional exclusion was added that applied to diagnoses that identify an unspecified site or side (meaning the code is defined by laterality or site specificity). There are ICD-10-CM codes that are specific to site, laterality, and proximal versus distal parts of the body. For example, L89.004, Pressure ulcer of unspecified elbow, stage 4, can be coded to identify whether the pressure ulcer is on the left or right elbow. ICD-10 CM coding guidelines state to report diagnoses to the greatest level of specificity. The home health clinician should be able to identify the specific side or body part involved through either direct assessment or of a query of the certifying physician.

Finally, an exclusion was added for some secondary diagnoses that would not be considered a comorbidity if reported with certain Z codes. For example, if Z96.651, presence of right artificial knee joint, is reported as secondary, it would not be considered a comorbidity if Z47.1, aftercare following joint replacement surgery, was reported as the principal diagnosis. The secondary diagnosis in this scenario is not a comorbidity because this secondary diagnosis explains the reason for the aftercare. We are utilizing this approach to minimize the unintended consequence of providers reporting comorbidities that are duplicative of the

⁹¹ Appendix Exhibit A9-1, "Overview of the Home Health Groupings Model", 2016. 12-23-12-26. <https://www.cms.gov/center/provider-type/home-health-agency-hha-center.html>.

⁹² Mosby's Medical Dictionary, 9th edition. ©2009, Elsevier.

⁹³ Cooper, S., McLean, G., Guthrie, B., McConnachie, A., Mercer, S., Sullivan, F.,

Morrison, J. (2015). "Multiple physical and mental health comorbidity in adults with intellectual disabilities". *BMC Family Practice*. 16(110), 1-11. doi 10.1186/s12875-015-0329-3.

⁹⁴ Fried, L., Ferrucci, L., Darer, J., Williamson, J., Anderson, G. (2004). "Untangling the Concepts of Disability, Frailty, and Comorbidity: Implications for Improved Targeting and Care". *Journal of Gerontology*. 59(3), 255-263.

⁹⁵ Starfield, B., Lemke, K., Bernhardt, T., Folds, S., Forrest, C., Weiner, J. (2003). "Comorbidity: Implications for the Importance of Primary Care in Case Management". *Annals of Family Medicine*. 1(1), 8-14.

⁹⁶ <http://www.cdc.gov/chronicdisease/about/multiple-chronic.html>.

principal diagnosis, or are a further description of the principal diagnosis, which could potentially overestimate the actual resources needed for a home health period and could result in inaccurate payment.

Using the research from the comprehensive literature review, we identified common chronic comorbid conditions frequently cited as drivers of increased health care resource utilization, including coronary artery disease, congestive heart failure, diabetes, COPD, asthma, chronic wounds, and depression.⁹⁷ In addition to chronic comorbid conditions, other acute comorbid conditions have been shown to affect overall resource utilization as well. These conditions include pneumonia, Clostridium difficile (c-diff), and Methicillin-resistant Staphylococcus aureus (MRSA).⁹⁸ After compiling a list of both acute and chronic comorbid diagnoses that could affect home health resource utilization, we conducted initial analyses looking at controlling for the presence of the individual diagnoses. However, these analyses showed some counterintuitive relationships with resource use, meaning the presence of certain comorbidities showed that there would be less resource use than if the comorbidity was not present.

Because the core of the HHGM is a clinical one, CMS clinicians utilized the principles of patient assessment by body systems and their associated diseases, conditions, and injuries as a way to examine potential clinically relevant relationships. Next, we combined those individual diagnoses into larger categories utilizing the body systems as a clinically intuitive way to consider what diagnoses potentially could impact the home health plan of care and resource utilization. When combining the individual diagnoses into larger comorbidity categories, the counterintuitive relationships decreased. These broad body system categories include conditions, diseases, and injuries that affect each of the individual body systems (for example, heart disease). Neoplasms and infectious diseases were given their own

discrete categories because of their potential to affect more than one body system. The broad categories used to group comorbidities within the HHGM were further refined by grouping similar diagnoses within the broad categories into subcategories. The subcategories allowed for additional refinement of diagnoses to include as part of the home health specific list. Subcategories were distinguished primarily (but not exclusively) by the first three characters of the ICD-10-CM diagnosis code to represent related conditions within the same body system. For example, subcategory Heart 10 includes diagnoses associated with various cardiac arrhythmias. The home health specific comorbidity list includes 13 broad body system based categories and 116 total subcategories using ICD-10-CM diagnosis codes. The broad categories used to group comorbidities within the HHGM include the following:

- Heart Disease (11 subcategories).
- Respiratory Disease (9 subcategories).
- Circulatory Disease and Blood Disorders (12 subcategories).
- Cerebral Vascular Disease (4 subcategories).
- Gastrointestinal Disease (9 subcategories).
- Neurological Disease and Associated Conditions (11 subcategories).
- Endocrine Disease (6 subcategories).
- Neoplasm (24 subcategories).
- Genitourinary and Renal Disease (5 subcategories).
- Skin Disease (5 subcategories).
- Musculoskeletal Disease or Injury (5 subcategories).
- Behavioral Health (11 subcategories).
- Infectious Disease (4 subcategories).

The secondary diagnoses listed on the OASIS that are attributed to any one of the listed subcategories were used to identify whether a period fell into one or more comorbidity categories and subcategories.

For the purpose of evaluating these identified comorbidities for inclusion in the HHGM, we assigned the CY 2016 home health periods that reported a secondary diagnosis included on this home health specific list to a comorbidity subcategory and subsequently dropped any subcategories that were in less than 0.1 percent of periods. This was done because low volume leads to instability in our estimates of how resource use is related to the comorbidity. A regression model was used to determine the relationship between the remaining subcategories and resource use. After this analysis, we dropped comorbidity subcategories that

were not statistically significant with regards to their relationship to resource use (a coefficient with a p-value greater than 0.05). After these exclusions, we kept the subcategories associated with increased resource use that was at least as high as the median resource use, as they indicated a direct relationship between the comorbidity subcategories and resource utilization. These remaining subcategories would receive a comorbidity adjustment. As such, there are 15 subcategories that meet the current criteria for the comorbidity adjustment in the HHGM. This is a decreased number of subcategories that were presented in the technical report where 29 subcategories met the criteria to qualify for the comorbidity adjustment. The comorbidity analysis presented in the technical report was based on CY 2013 data and used ICD-9-CM diagnosis codes. There are several potential reasons for this decrease including that the analysis exclusions for the 2016 analysis were slightly different than were used in the technical report. Another potential reason for the decrease in subcategories may be due to diagnosis exclusions based on changes from ICD-9-CM to ICD-10-CM with regards to specificity. Some of this decrease could be related to the changes in case-mix weights from 2013 to 2016 where secondary conditions that received clinical points in 2013 may not have had any associated points in 2016 and hence, there would be no incentive to report those conditions. The analysis on the CY 2013 and CY 2016 data, including all of the diagnoses and their assigned subcategories is posted on the HHA Center Web page.⁹⁹ The 15 subcategories included in the comorbidity adjustment in the HHGM are as follows:

- Heart Disease 1: Includes hypertensive heart disease.
- Cerebral Vascular Disease 4: Includes sequelae of cerebrovascular disease.
- Circulatory Disease and Blood Disorders 9: Includes venous embolisms and thrombosis.
- Circulatory Disease and Blood Disorders 10: Includes varicose veins of lower extremities with ulcers and inflammation, and esophageal varices.
- Circulatory Disease and Blood Disorders 11: Includes lymphedema.
- Endocrine Disease 2: Includes diabetes with complications due to an underlying condition.
- Neoplasm 18: Includes secondary malignant neoplasms.

⁹⁷ Center for Healthcare Research and Transformation. (2010) "Healthcare Cost Drivers: Chronic Disease, Comorbidity, and Health Risk Factors in the U.S. and Michigan." <http://www.chrt.org/publication/health-care-cost-drivers-chronic-disease-comorbidity-health-risk-factors-u-s-michigan/>.

⁹⁸ Drikoningsen, J., Rohde, G., (2010). "Pneumococcal Infection in Adults: Burden of Disease". Clinical Microbiology and Infection. 45–51. Kyne, L., Hamel, M.B., Polavaram, R., Kelly, C. (2002). "Health Care Costs and Mortality Associated with Nosocomial Diarrhea due to Clostridium difficile". Clinical Infectious Diseases. 346–353.

⁹⁹ <https://www.cms.gov/center/provider-type/home-health-agency-hha-center.html>.

- Neurological Disease and Associated Conditions 5: Includes secondary parkinsonism.
- Neurological Disease and Associated Conditions 7: Includes encephalitis, myelitis, encephalomyelitis, and hemiplegia, paraplegia, and quadriplegia.
- Neurological Disease and Associated Conditions 10: Includes diabetes with neurological complications.

- Respiratory Disease 7: Includes pneumonia, pneumonitis, and pulmonary edema.
- Skin Disease 1: Includes cutaneous abscesses, and cellulitis.
- Skin Disease 2: Includes stage one pressure ulcers.
- Skin Disease 3: Includes atherosclerosis with gangrene.
- Skin Disease 4: Includes unstageable and stages two through four pressure ulcers.

We propose that if a period had at least one secondary diagnosis reported on the home health claim that fell into

one of the 15 subcategories, that period would receive a comorbidity adjustment to account for higher costs associated with the comorbidity. The comorbidity adjustment amount would be the same across all of the subcategories. A period would receive only one comorbidity adjustment regardless of the number of secondary diagnoses reported on the home health claim that fell into one of the 15 subcategories. Table 39 shows information on resource use for periods with and without the comorbidity adjustment.

TABLE 39—FREQUENCY OF COMORBIDITY GROUPS AND DISTRIBUTION OF AVERAGE RESOURCE USE

Comorbidity group	Mean resource use	Frequency of periods	Percent of periods	Standard deviation of resource use	25th Percentile of resource use	Median resource use	75th Percentile of resource use
No Comorbidity Adjustment	\$1,534.17	7,365,806	85.23	\$1,228.43	\$1,227.35	\$653.57	\$2,061.88
Comorbidity Adjustment	1,881.60	1,276,301	14.77	1,562.89	1,484.39	803.15	2,475.20
Total	1,585.48	8,642,107	100.00	1,289.23	1,262.65	671.96	2,119.49

The HHGM payment adjustment for comorbidities is predicated on the presence of one of the identified diagnoses within the subcategories associated with increased resource use at or above the median. If there is no reported diagnosis that meets the comorbidity adjustment criteria, the period would not qualify for the payment adjustment. We consider this comorbidity adjustment component of the proposed HHGM to be fluid, where OASIS-reported secondary diagnoses may be removed from, or added to the home health specific comorbidity list dependent upon the relationship between the comorbidity and resource costs. If the HHGM is finalized and implemented, we anticipate there may be behavioral shifts in secondary diagnosis reporting and the proposed comorbidity list and its associated subcategories may change to capture resource utilization associated with these or other conditions. We invite comments on the proposed comorbidity diagnoses, including additions or subtractions to the proposed home health specific list, and this comorbidity adjustment approach under the HHGM.

9. Change in the Low-Utilization Payment Adjustment (LUPA) Threshold

An episode with four or fewer visits is paid the national per visit amount by

discipline, adjusted by the appropriate wage index based on the site of service of the beneficiary, instead of the full episode amount. Such payment adjustments are called Low Utilization Payment Adjustments (LUPAs). While the proposed HHGM system would still include LUPA payments, we are proposing that the approach to calculating the LUPA thresholds would change in the HHGM because of the proposed change in the unit of payment to 30-day periods from 60-day episodes. Whereas LUPAs are paid for all episodes consisting of four or fewer visits under the current payment system, in order to receive full episode amount under the HHGM (rather than receive a LUPA where the episode would be paid the national per visit amount by discipline) we propose to vary the LUPA threshold for a 30-day period under the HHGM depending on the HHGM payment group to which it is assigned. The 30-day periods have substantially more instances of four or fewer visits than 60-day episodes. To create LUPA thresholds, 30-day periods (including those that were LUPAs in the current payment system) were grouped into the 144 different HHGM payment groups. For each payment group, we propose to set the LUPA threshold at the 10th percentile value of visits or 2 visits, whichever is higher. In the current

payment system approximately 8 percent of episodes are LUPAs. Under the HHGM, we propose the 10th percentile value of visits or 2 visits, whichever is higher, to target approximately the same percentage of LUPAs (approximately 7 percent of 30-day periods would be LUPAs (assuming no behavior change)).

For example, for 30-day periods of care in the payment group corresponding to “MMTA—Functional Level Medium—Early Timing—Institutional Admission—No Comorbidity Adjustment”, the threshold is four visits. If 30-day periods assigned to that particular payment group had three or fewer visits they would be paid using the national per-visit rates in section III.C.3 of this proposed rule instead of the case-mix adjusted 30-day payment amount. We propose that the LUPA thresholds for each HHGM payment group would be re-evaluated every year based on the most current, complete utilization data available. The LUPA thresholds, based on the most current utilization data available (CY 2016 data as of March 17, 2017), for each corresponding HIPPS code, are listed in Table 40. We would propose updated LUPA thresholds using the most current, complete utilization data available at the time of rulemaking.

TABLE 40—PROPOSED LUPA THRESHOLDS FOR THE PROPOSED HHGM PAYMENT GROUPS BASED ON CY 2016 UTILIZATION DATA

HIPPS	Clinical group and functional level	Timing and admission source	Comorbidity adjustment	Threshold (10th percentile or 2—whichever is higher)
1AAN	MMTA—Low	Early—Community	No	4
1AAY	MMTA—Low	Early—Community	Yes	4
1ABN	MMTA—Medium	Early—Community	No	4
1ABY	MMTA—Medium	Early—Community	Yes	4
1ACN	MMTA—High	Early—Community	No	4
1ACY	MMTA—High	Early—Community	Yes	4
1BAN	Neuro—Low	Early—Community	No	4
1BAY	Neuro—Low	Early—Community	Yes	5
1BBN	Neuro—Medium	Early—Community	No	5
1BBY	Neuro—Medium	Early—Community	Yes	5
1BCN	Neuro—High	Early—Community	No	5
1BCY	Neuro—High	Early—Community	Yes	5
1CAN	Wound—Low	Early—Community	No	5
1CAY	Wound—Low	Early—Community	Yes	4
1CBN	Wound—Medium	Early—Community	No	5
1CBY	Wound—Medium	Early—Community	Yes	5
1CCN	Wound—High	Early—Community	No	5
1CCY	Wound—High	Early—Community	Yes	5
1DAN	Complex—Low	Early—Community	No	3
1DAY	Complex—Low	Early—Community	Yes	3
1DBN	Complex—Medium	Early—Community	No	3
1DBY	Complex—Medium	Early—Community	Yes	3
1DCN	Complex—High	Early—Community	No	3
1DCY	Complex—High	Early—Community	Yes	3
1EAN	MS Rehab—Low	Early—Community	No	5
1EAY	MS Rehab—Low	Early—Community	Yes	5
1EBN	MS Rehab—Medium	Early—Community	No	5
1EBY	MS Rehab—Medium	Early—Community	Yes	5
1ECN	MS Rehab—High	Early—Community	No	5
1ECY	MS Rehab—High	Early—Community	Yes	5
1FAN	Behavioral Health—Low	Early—Community	No	3
1FAY	Behavioral Health—Low	Early—Community	Yes	3
1FBN	Behavioral Health—Medium	Early—Community	No	4
1FBY	Behavioral Health—Medium	Early—Community	Yes	4
1FCN	Behavioral Health—High	Early—Community	No	4
1FCY	Behavioral Health—High	Early—Community	Yes	4
2AAN	MMTA—Low	Early—Institutional	No	3
2AAY	MMTA—Low	Early—Institutional	Yes	4
2ABN	MMTA—Medium	Early—Institutional	No	4
2ABY	MMTA—Medium	Early—Institutional	Yes	5
2ACN	MMTA—High	Early—Institutional	No	4
2ACY	MMTA—High	Early—Institutional	Yes	4
2BAN	Neuro—Low	Early—Institutional	No	5
2BAY	Neuro—Low	Early—Institutional	Yes	5
2BBN	Neuro—Medium	Early—Institutional	No	6
2BBY	Neuro—Medium	Early—Institutional	Yes	6
2BCN	Neuro—High	Early—Institutional	No	5
2BCY	Neuro—High	Early—Institutional	Yes	5
2CAN	Wound—Low	Early—Institutional	No	4
2CAY	Wound—Low	Early—Institutional	Yes	4
2CBN	Wound—Medium	Early—Institutional	No	5
2CBY	Wound—Medium	Early—Institutional	Yes	5
2CCN	Wound—High	Early—Institutional	No	4
2CCY	Wound—High	Early—Institutional	Yes	5
2DAN	Complex—Low	Early—Institutional	No	3
2DAY	Complex—Low	Early—Institutional	Yes	4
2DBN	Complex—Medium	Early—Institutional	No	4
2DBY	Complex—Medium	Early—Institutional	Yes	4
2DCN	Complex—High	Early—Institutional	No	4
2DCY	Complex—High	Early—Institutional	Yes	4
2EAN	MS Rehab—Low	Early—Institutional	No	5
2EAY	MS Rehab—Low	Early—Institutional	Yes	5
2EBN	MS Rehab—Medium	Early—Institutional	No	6
2EBY	MS Rehab—Medium	Early—Institutional	Yes	6
2ECN	MS Rehab—High	Early—Institutional	No	6
2ECY	MS Rehab—High	Early—Institutional	Yes	7
2FAN	Behavioral Health—Low	Early—Institutional	No	3

TABLE 40—PROPOSED LUPA THRESHOLDS FOR THE PROPOSED HHGM PAYMENT GROUPS BASED ON CY 2016 UTILIZATION DATA—Continued

HIPPS	Clinical group and functional level	Timing and admission source	Comorbidity adjustment	Threshold (10th percentile or 2—whichever is higher)
2FAY	Behavioral Health—Low	Early—Institutional	Yes	3
2FBN	Behavioral Health—Medium	Early—Institutional	No	4
2FBY	Behavioral Health—Medium	Early—Institutional	Yes	5
2FCN	Behavioral Health—High	Early—Institutional	No	4
2FCY	Behavioral Health—High	Early—Institutional	Yes	4
3AAN	MMTA—Low	Late—Community	No	2
3AAY	MMTA—Low	Late—Community	Yes	2
3ABN	MMTA—Medium	Late—Community	No	2
3ABY	MMTA—Medium	Late—Community	Yes	2
3ACN	MMTA—High	Late—Community	No	2
3ACY	MMTA—High	Late—Community	Yes	2
3BAN	Neuro—Low	Late—Community	No	2
3BAY	Neuro—Low	Late—Community	Yes	2
3BBN	Neuro—Medium	Late—Community	No	2
3BBY	Neuro—Medium	Late—Community	Yes	3
3BCN	Neuro—High	Late—Community	No	2
3BCY	Neuro—High	Late—Community	Yes	3
3CAN	Wound—Low	Late—Community	No	3
3CAY	Wound—Low	Late—Community	Yes	3
3CBN	Wound—Medium	Late—Community	No	3
3CBY	Wound—Medium	Late—Community	Yes	3
3CCN	Wound—High	Late—Community	No	3
3CCY	Wound—High	Late—Community	Yes	3
3DAN	Complex—Low	Late—Community	No	2
3DAY	Complex—Low	Late—Community	Yes	2
3DBN	Complex—Medium	Late—Community	No	2
3DBY	Complex—Medium	Late—Community	Yes	2
3DCN	Complex—High	Late—Community	No	2
3DCY	Complex—High	Late—Community	Yes	2
3EAN	MS Rehab—Low	Late—Community	No	2
3EAY	MS Rehab—Low	Late—Community	Yes	2
3EBN	MS Rehab—Medium	Late—Community	No	2
3EBY	MS Rehab—Medium	Late—Community	Yes	2
3ECN	MS Rehab—High	Late—Community	No	2
3ECY	MS Rehab—High	Late—Community	Yes	3
3FAN	Behavioral Health—Low	Late—Community	No	2
3FAY	Behavioral Health—Low	Late—Community	Yes	2
3FBN	Behavioral Health—Medium	Late—Community	No	2
3FBY	Behavioral Health—Medium	Late—Community	Yes	2
3FCN	Behavioral Health—High	Late—Community	No	2
3FCY	Behavioral Health—High	Late—Community	Yes	3
4AAN	MMTA—Low	Late—Institutional	No	3
4AAY	MMTA—Low	Late—Institutional	Yes	3
4ABN	MMTA—Medium	Late—Institutional	No	3
4ABY	MMTA—Medium	Late—Institutional	Yes	3
4ACN	MMTA—High	Late—Institutional	No	3
4ACY	MMTA—High	Late—Institutional	Yes	3
4BAN	Neuro—Low	Late—Institutional	No	4
4BAY	Neuro—Low	Late—Institutional	Yes	4
4BBN	Neuro—Medium	Late—Institutional	No	4
4BBY	Neuro—Medium	Late—Institutional	Yes	4
4BCN	Neuro—High	Late—Institutional	No	4
4BCY	Neuro—High	Late—Institutional	Yes	4
4CAN	Wound—Low	Late—Institutional	No	3
4CAY	Wound—Low	Late—Institutional	Yes	3
4CBN	Wound—Medium	Late—Institutional	No	4
4CBY	Wound—Medium	Late—Institutional	Yes	4
4CCN	Wound—High	Late—Institutional	No	4
4CCY	Wound—High	Late—Institutional	Yes	4
4DAN	Complex—Low	Late—Institutional	No	2
4DAY	Complex—Low	Late—Institutional	Yes	3
4DBN	Complex—Medium	Late—Institutional	No	3
4DBY	Complex—Medium	Late—Institutional	Yes	3
4DCN	Complex—High	Late—Institutional	No	3
4DCY	Complex—High	Late—Institutional	Yes	3
4EAN	MS Rehab—Low	Late—Institutional	No	4
4EAY	MS Rehab—Low	Late—Institutional	Yes	4

TABLE 40—PROPOSED LUPA THRESHOLDS FOR THE PROPOSED HHGM PAYMENT GROUPS BASED ON CY 2016 UTILIZATION DATA—Continued

HIPPS	Clinical group and functional level	Timing and admission source	Comorbidity adjustment	Threshold (10th percentile or 2—whichever is higher)
4EBN	MS Rehab—Medium	Late—Institutional	No	4
4EBY	MS Rehab—Medium	Late—Institutional	Yes	4
4ECN	MS Rehab—High	Late—Institutional	No	4
4ECY	MS Rehab—High	Late—Institutional	Yes	5
4FAN	Behavioral Health—Low	Late—Institutional	No	2
4FAY	Behavioral Health—Low	Late—Institutional	Yes	3
4FBN	Behavioral Health—Medium	Late—Institutional	No	3
4FBY	Behavioral Health—Medium	Late—Institutional	Yes	3
4FCN	Behavioral Health—High	Late—Institutional	No	3
4FCY	Behavioral Health—High	Late—Institutional	Yes	3

We invite public comments on the LUPA threshold methodology proposed for the HHGM and the associated regulations text changes in section VIII. of this proposed rule.

10. HH PPS Case-Mix Weights Under the HHGM

Section 1895(b)(4)(B) of the Act requires the Secretary to establish appropriate case mix adjustment factors for home health services in a manner that explains a significant amount of the variation in cost among different units of services. We are proposing the HHGM case-mix adjustment methodology, which sorts 30-day periods of care into different payment groups based on five categories (admission source, timing, clinical group, functional level, and comorbidity group), for 30-day periods of care that begin on or after January 1, 2019. In combination, this would yield a total of 144 HHGM payment groups, which we would still refer to as Home Health Resource Groups (HHRGs) under

the HHGM. To generate HHGM case-mix weights, we utilized a data file based on home health episodes of care, as reported in Medicare home health claims, as well as OASIS assessment data. The claims data provide episode-level data, as well as visit-level data. The claims also provide data on whether NRS was provided during the episode and the total charges for NRS. We determined the case-mix weight for each of the different HHGM payment groups by regressing resource use on a series of indicator variables for each of the five categories listed above using a fixed effects model. The regression measures resource use with the proposed Cost per Minute (CPS) + NRS approach outlined in section III.E.2 of this proposed rule.

To normalize the results from the fixed effects regression model, we divided the predicted resource use for each 30-day period by the overall average resource use for all 30-day

periods used to estimate the model to calculate the case mix weight of all 30-day periods within a particular payment group, where each payment group is defined as the unique combination of the subgroups within the five HHGM categories (admission source, timing of the episode, clinical grouping, functional level, and comorbidity adjustment). The case-mix weight is then used to adjust the 30-day payment rate to determine each 30-day period payment. Table 41 shows the coefficients of the payment regression used to generate the weights, and the coefficients divided by average resource use. Information can be found in section III.E.6 of this proposed rule for the clinical groups, section III.E.7 of this proposed rule for the functional levels, section III.E.5 of this proposed rule for admission source, section III.E.4 of this proposed rule for episode timing, and section III.E.8 of this proposed rule for the comorbidity adjustment.

TABLE 41—COEFFICIENT OF PAYMENT REGRESSION AND COEFFICIENT DIVIDED BY AVERAGE RESOURCE USE FOR HHGM PAYMENT GROUP

	Coefficient	Coefficient divided by average resource use
Clinical Group and Functional Level (MMTA—Low is excluded)		
MMTA—Medium	\$238.93	0.151
MMTA—High	434.36	0.274
Behavioral Health—Low	– 116.43	– 0.073
Behavioral Health—Medium	177.47	0.112
Behavioral Health—High	350.98	0.221
Complex—Low	99.82	0.063
Complex—Medium	472.79	0.298
Complex—High	638.62	0.403
MS Rehab—Low	154.72	0.098
MS Rehab—Medium	353.44	0.223
MS Rehab—High	597.31	0.377
Neuro—Low	356.33	0.225
Neuro—Medium	636.52	0.401
Neuro—High	804.50	0.507
Wound—Low	582.68	0.368

TABLE 41—COEFFICIENT OF PAYMENT REGRESSION AND COEFFICIENT DIVIDED BY AVERAGE RESOURCE USE FOR HHGM PAYMENT GROUP—Continued

	Coefficient	Coefficient divided by average resource use
Wound—Medium	812.76	0.513
Wound—High	1,048.55	0.661
Referral Source With Timing (Community Early excluded)		
Community Late	– 618.74	– 0.390
Institutional Early	271.07	0.171
Institutional Late	83.61	0.053
Comorbidity Adjustment (No Comorbidity Adjustment Group is excluded)		
Comorbidity Adjustment Group	244.01	0.154
Constant	1,533.33	0.967
N	8,642,107	
Adjusted R2	0.2704	
Average Resource Use	1,585.48	

Source: CY 2016 Medicare claims data for episodes ending on or before December 31, 2016 (as of March 17, 2017) for which we had a linked OASIS assessment. LUPA episodes, outlier episodes, and episodes with PEP adjustments were excluded.

Table 42 presents the case-mix weight for each HHRG in the regression model (from Table 46's coefficients). LUPA episodes, outlier episodes, and episodes with PEP adjustments were excluded. These are the case-mix weights for the HHGM based on the most current, complete data available (CY 2016 data as of March 17, 2017). We would propose updated case-mix weights using the latest CY 2017 data in the CY 2019 HH PPS proposed rule. LUPA information can be found in section III.E.9 of this proposed rule. Weights are determined by first calculating the predicted resource use for episodes with a particular combination of admission source, episode timing, clinical grouping, functional level, and

comorbidity adjustment. This combination specific calculation is then divided by the average resource use of all the episodes that were used to estimate, which is \$1,585.48. The resulting ratio represents the case-mix weight for that particular combination of a HHRG payment group. The adjusted R-squared value for this model is 0.2704. The adjusted R-squared value provides a measure of how well observed outcomes are replicated by the model, based on the proportion of total variation of outcomes explained by the model. In this instance, the fixed effects regression model used to generate the case-mix weight under the HHGM predicts about 27 percent of the

variation in resource use in a given 30-day period of home health care.

As noted above, there are 144 different HHRG payment groups under the HHGM. There are 9 HHRG payment groups that represent roughly 50.5 percent of the total episodes. There are 33 HHRG payment groups that represent roughly 1.0 percent of total episodes. The HHRG payment group with the smallest weight has a weight of 0.5034 (community, late, behavioral health, low functional level, with no comorbidity adjustment). The HHRG payment group with the largest weight has a weight of 1.9533 (institutional admission, early, wound, high functional level, with comorbidity adjustment).

TABLE 42—CASE-MIX WEIGHTS FOR EACH HHRG PAYMENT GROUP, BASED ON 2016 DATA

HIPPS	Clinical group and functional level	Timing and admission source	Comorbidity adjustment	Weight based on CY 2016 data
1AAN	MMTA—Low	Early—Community	No	0.9671
1AAY	MMTA—Low	Early—Community	Yes	1.1210
1ABN	MMTA—Medium	Early—Community	No	1.1178
1ABY	MMTA—Medium	Early—Community	Yes	1.2717
1ACN	MMTA—High	Early—Community	No	1.2411
1ACY	MMTA—High	Early—Community	Yes	1.3950
1BAN	Neuro—Low	Early—Community	No	1.1919
1BAY	Neuro—Low	Early—Community	Yes	1.3458
1BBN	Neuro—Medium	Early—Community	No	1.3686
1BBY	Neuro—Medium	Early—Community	Yes	1.5225
1BCN	Neuro—High	Early—Community	No	1.4745
1BCY	Neuro—High	Early—Community	Yes	1.6284
1CAN	Wound—Low	Early—Community	No	1.3346
1CAY	Wound—Low	Early—Community	Yes	1.4885
1CBN	Wound—Medium	Early—Community	No	1.4797
1CBY	Wound—Medium	Early—Community	Yes	1.6336
1CCN	Wound—High	Early—Community	No	1.6284

TABLE 42—CASE-MIX WEIGHTS FOR EACH HHRG PAYMENT GROUP, BASED ON 2016 DATA—Continued

HIPPS	Clinical group and functional level	Timing and admission source	Comorbidity adjustment	Weight based on CY 2016 data
1CCY	Wound—High	Early—Community	Yes	1.7823
1DAN	Complex—Low	Early—Community	No	1.0301
1DAY	Complex—Low	Early—Community	Yes	1.1840
1DBN	Complex—Medium	Early—Community	No	1.2653
1DBY	Complex—Medium	Early—Community	Yes	1.4192
1DCN	Complex—High	Early—Community	No	1.3699
1DCY	Complex—High	Early—Community	Yes	1.5238
1EAN	MS Rehab—Low	Early—Community	No	1.0647
1EAY	MS Rehab—Low	Early—Community	Yes	1.2186
1EBN	MS Rehab—Medium	Early—Community	No	1.1900
1EBY	MS Rehab—Medium	Early—Community	Yes	1.3439
1ECN	MS Rehab—High	Early—Community	No	1.3438
1ECY	MS Rehab—High	Early—Community	Yes	1.4977
1FAN	Behavioral Health—Low	Early—Community	No	0.8937
1FAY	Behavioral Health—Low	Early—Community	Yes	1.0476
1FBN	Behavioral Health—Medium	Early—Community	No	1.0790
1FBY	Behavioral Health—Medium	Early—Community	Yes	1.2329
1FCN	Behavioral Health—High	Early—Community	No	1.1885
1FCY	Behavioral Health—High	Early—Community	Yes	1.3424
2AAN	MMTA—Low	Early—Institutional	No	1.1381
2AAY	MMTA—Low	Early—Institutional	Yes	1.2920
2ABN	MMTA—Medium	Early—Institutional	No	1.2888
2ABY	MMTA—Medium	Early—Institutional	Yes	1.4427
2ACN	MMTA—High	Early—Institutional	No	1.4120
2ACY	MMTA—High	Early—Institutional	Yes	1.5659
2BAN	Neuro—Low	Early—Institutional	No	1.3628
2BAY	Neuro—Low	Early—Institutional	Yes	1.5167
2BBN	Neuro—Medium	Early—Institutional	No	1.5395
2BBY	Neuro—Medium	Early—Institutional	Yes	1.6934
2BCN	Neuro—High	Early—Institutional	No	1.6455
2BCY	Neuro—High	Early—Institutional	Yes	1.7994
2CAN	Wound—Low	Early—Institutional	No	1.5056
2CAY	Wound—Low	Early—Institutional	Yes	1.6595
2CBN	Wound—Medium	Early—Institutional	No	1.6507
2CBY	Wound—Medium	Early—Institutional	Yes	1.8046
2CCN	Wound—High	Early—Institutional	No	1.7994
2CCY	Wound—High	Early—Institutional	Yes	1.9533
2DAN	Complex—Low	Early—Institutional	No	1.2010
2DAY	Complex—Low	Early—Institutional	Yes	1.3549
2DBN	Complex—Medium	Early—Institutional	No	1.4363
2DBY	Complex—Medium	Early—Institutional	Yes	1.5902
2DCN	Complex—High	Early—Institutional	No	1.5409
2DCY	Complex—High	Early—Institutional	Yes	1.6948
2EAN	MS Rehab—Low	Early—Institutional	No	1.2357
2EAY	MS Rehab—Low	Early—Institutional	Yes	1.3896
2EBN	MS Rehab—Medium	Early—Institutional	No	1.3610
2EBY	MS Rehab—Medium	Early—Institutional	Yes	1.5149
2ECN	MS Rehab—High	Early—Institutional	No	1.5148
2ECY	MS Rehab—High	Early—Institutional	Yes	1.6687
2FAN	Behavioral Health—Low	Early—Institutional	No	1.0646
2FAY	Behavioral Health—Low	Early—Institutional	Yes	1.2185
2FBN	Behavioral Health—Medium	Early—Institutional	No	1.2500
2FBY	Behavioral Health—Medium	Early—Institutional	Yes	1.4039
2FCN	Behavioral Health—High	Early—Institutional	No	1.3594
2FCY	Behavioral Health—High	Early—Institutional	Yes	1.5133
3AAN	MMTA—Low	Late—Community	No	0.5769
3AAY	MMTA—Low	Late—Community	Yes	0.7308
3ABN	MMTA—Medium	Late—Community	No	0.7276
3ABY	MMTA—Medium	Late—Community	Yes	0.8815
3ACN	MMTA—High	Late—Community	No	0.8508
3ACY	MMTA—High	Late—Community	Yes	1.0047
3BAN	Neuro—Low	Late—Community	No	0.8016
3BAY	Neuro—Low	Late—Community	Yes	0.9555
3BBN	Neuro—Medium	Late—Community	No	0.9783
3BBY	Neuro—Medium	Late—Community	Yes	1.1322
3BCN	Neuro—High	Late—Community	No	1.0843
3BCY	Neuro—High	Late—Community	Yes	1.2382
3CAN	Wound—Low	Late—Community	No	0.9444
3CAY	Wound—Low	Late—Community	Yes	1.0983
3CBN	Wound—Medium	Late—Community	No	1.0895

TABLE 42—CASE-MIX WEIGHTS FOR EACH HHRG PAYMENT GROUP, BASED ON 2016 DATA—Continued

HIPPS	Clinical group and functional level	Timing and admission source	Comorbidity adjustment	Weight based on CY 2016 data
3CBY	Wound—Medium	Late—Community	Yes	1.2434
3CCN	Wound—High	Late—Community	No	1.2382
3CCY	Wound—High	Late—Community	Yes	1.3921
3DAN	Complex—Low	Late—Community	No	0.6398
3DAY	Complex—Low	Late—Community	Yes	0.7937
3DBN	Complex—Medium	Late—Community	No	0.8751
3DBY	Complex—Medium	Late—Community	Yes	1.0290
3DCN	Complex—High	Late—Community	No	0.9796
3DCY	Complex—High	Late—Community	Yes	1.1335
3EAN	MS Rehab—Low	Late—Community	No	0.6744
3EAY	MS Rehab—Low	Late—Community	Yes	0.8283
3EBN	MS Rehab—Medium	Late—Community	No	0.7998
3EBY	MS Rehab—Medium	Late—Community	Yes	0.9537
3ECN	MS Rehab—High	Late—Community	No	0.9536
3ECY	MS Rehab—High	Late—Community	Yes	1.1075
3FAN	Behavioral Health—Low	Late—Community	No	0.5034
3FAY	Behavioral Health—Low	Late—Community	Yes	0.6573
3FBN	Behavioral Health—Medium	Late—Community	No	0.6888
3FBY	Behavioral Health—Medium	Late—Community	Yes	0.8427
3FCN	Behavioral Health—High	Late—Community	No	0.7982
3FCY	Behavioral Health—High	Late—Community	Yes	0.9521
4AAN	MMTA—Low	Late—Institutional	No	1.0198
4AAY	MMTA—Low	Late—Institutional	Yes	1.1737
4ABN	MMTA—Medium	Late—Institutional	No	1.1705
4ABY	MMTA—Medium	Late—Institutional	Yes	1.3244
4ACN	MMTA—High	Late—Institutional	No	1.2938
4ACY	MMTA—High	Late—Institutional	Yes	1.4477
4BAN	Neuro—Low	Late—Institutional	No	1.2446
4BAY	Neuro—Low	Late—Institutional	Yes	1.3985
4BBN	Neuro—Medium	Late—Institutional	No	1.4213
4BBY	Neuro—Medium	Late—Institutional	Yes	1.5752
4BCN	Neuro—High	Late—Institutional	No	1.5273
4BCY	Neuro—High	Late—Institutional	Yes	1.6812
4CAN	Wound—Low	Late—Institutional	No	1.3874
4CAY	Wound—Low	Late—Institutional	Yes	1.5413
4CBN	Wound—Medium	Late—Institutional	No	1.5325
4CBY	Wound—Medium	Late—Institutional	Yes	1.6864
4CCN	Wound—High	Late—Institutional	No	1.6812
4CCY	Wound—High	Late—Institutional	Yes	1.8351
4DAN	Complex—Low	Late—Institutional	No	1.0828
4DAY	Complex—Low	Late—Institutional	Yes	1.2367
4DBN	Complex—Medium	Late—Institutional	No	1.3180
4DBY	Complex—Medium	Late—Institutional	Yes	1.4719
4DCN	Complex—High	Late—Institutional	No	1.4226
4DCY	Complex—High	Late—Institutional	Yes	1.5765
4EAN	MS Rehab—Low	Late—Institutional	No	1.1174
4EAY	MS Rehab—Low	Late—Institutional	Yes	1.2713
4EBN	MS Rehab—Medium	Late—Institutional	No	1.2428
4EBY	MS Rehab—Medium	Late—Institutional	Yes	1.3967
4ECN	MS Rehab—High	Late—Institutional	No	1.3966
4ECY	MS Rehab—High	Late—Institutional	Yes	1.5505
4FAN	Behavioral Health—Low	Late—Institutional	No	0.9464
4FAY	Behavioral Health—Low	Late—Institutional	Yes	1.1003
4FBN	Behavioral Health—Medium	Late—Institutional	No	1.1318
4FBY	Behavioral Health—Medium	Late—Institutional	Yes	1.2857
4FCN	Behavioral Health—High	Late—Institutional	No	1.2412
4FCY	Behavioral Health—High	Late—Institutional	Yes	1.3951

Source: CY 2016 Medicare claims data for episodes ending on or before December 31, 2016 for which we had a linked OASIS assessment. LUPA episodes, outlier episodes, and episodes with PEP adjustments were excluded.

We invite comments on the proposed case-mix weight methodology under the HHGM.

11. Low-Utilization Payment Adjustment (LUPA) Add-On Payments and Partial Payment Adjustments Under the HHGM

LUPA episodes that occur as the only episode or as an initial episode in a sequence of adjacent episodes are

adjusted by applying an additional amount to the LUPA payment before adjusting for area wage differences. Under the HHGM, we propose the LUPA add-on factors will remain the same as the current payment system, described in section III.C.3. of this

proposed rule. We propose to multiply the per-visit payment amount for the first SN, PT, or SLP visit in LUPA episodes that occur as the only episode or an initial episode in a sequence of adjacent episodes by the appropriate factor (1.8451 for SN, 1.6700 for PT, and 1.6266 for SLP) to determine the LUPA add-on payment amount. For example, for LUPA episodes that occur as the only episode or an initial episode in a sequence of adjacent episodes in CY 2019, if the first skilled visit is SN, the payment for that visit would be the CY 2019 per-visit rate for SN, multiplied by 1.8451, subject to area wage adjustment.

The current partial episode payment (PEP) adjustment is a proportion of the episode payment and is based on the span of days including the start-of-care date or first billable service date through and including the last billable service date under the original plan of care before the intervening event in a home health beneficiary's care defined as:

- A beneficiary elected transfer, or
- A discharge and return to home

health that would warrant, for purposes of payment, a new OASIS assessment, physician certification of eligibility, and a new plan of care.

For 30-day periods of care, we propose the process for partial payment adjustments would remain the same as the existing policies pertaining to partial episode payments. When a new 30-day period begins due to the intervening event of the beneficiary elected transfer or there was a discharge and return to home health during the 30-day period, we propose the original 30-day period would be proportionally adjusted to reflect the length of time the beneficiary remained under the agency's care prior to the intervening event. The proportional payment is the partial payment adjustment. The partial payment adjustment is calculated by using the span of days (first billable service date through and including the last billable service date) under the original plan of care as a proportion of 30. The proportion is multiplied by the original case-mix and wage index to produce the 30-day payment.

12. Payments for High-Cost Outliers Under the HHGM

As described in section III.D. of this proposed rule, section 1895(b)(5) of the Act allows for the provision of an addition or adjustment to the home health payment amount in the case of outliers because of unusual variations in the type or amount of medically necessary care. The history of and current methodology for payment of high-cost outliers under the HH PPS is described in detail in section III.D. of

this proposed rule. We are proposing to maintain the current methodology for payment of high-cost outliers upon implementation of the HHGM in CY 2019 and we would calculate payment for high-cost outliers on 30-day periods of care.

Simulating payments using preliminary CY 2016 claims data and the CY 2018 payment rates, we estimate that outlier payments under the proposed HHGM with 30-day periods of care would comprise approximately 4.50 percent of total HH PPS payments in CY 2018. Given the statutory requirement to target up to, but no more than, 2.5 percent of total payments as outlier payments, we currently estimate that the FDL ratio under the HHGM would need to change from 0.55 to 0.93. However, given the proposed implementation of the HHGM for 30-day periods of care beginning on or after January 1, 2019, we will update our estimate of outlier payments as a percent of total HH PPS payments using the most current and complete utilization data available at the time of CY 2019 rate-setting. We would propose a change in the FDL ratio for CY 2019, if needed.

We invite public comments on maintaining the current outlier payment methodology outlined in section III.D. of this proposed rule for the proposed HHGM and the associated changes in the regulations text as described in section III.E.13 of this proposed rule.

13. Conforming Regulations Text Revisions for the Implementation of the HHGM in CY 2019

We are proposing to make a number of revisions to the regulations to implement the HHGM for periods beginning on or after January 1, 2019, as outlined in sections III.E.1. through III.E.12. of this proposed rule. We propose to make conforming changes in § 409.43 and part 484 subpart E to revise the unit of service from a 60-day episode to a 30-day period. In addition, we are proposing to restructure § 484.205. These revisions would be effective on January 1, 2019. We are not proposing any revisions to the regulations for CY 2018. These revisions and others are discussed below.

Specifically, we propose to:

- Revise § 409.43, which outlines plan of care requirements. We propose to revise several paragraphs to phase out the unit of service from a 60-day episode for episodes beginning on or before December 31, 2018, and to implement a 30-day period as the new unit of service for periods beginning on or after January 1, 2019 under the HHGM.

- Revise the definitions of rural area and urban area in § 484.202 to remove “with respect to home health episodes ending on or after January 1, 2006” from each definition, as this verbiage is no longer necessary.

- Restructure § 484.205 to provide more logical organization. Specifically, we propose to add paragraphs to paragraph (b) to define the unit of payment. We propose to move language which addresses the requirement for OASIS submission from § 484.210 and insert it into § 484.205 as new paragraph (c). We also propose to add paragraph (f) to discuss split percentage payments under the current model and the proposed HHGM. In addition, we propose to revise § 484.205 to remove references to “60-day episode” and to refer more generally to the “national, standardized prospective payment”. While we are proposing to revise § 484.205 to account for the change in the unit of payment under the HH PPS for CY 2019, we are not proposing to change the requirements or policies relating to durable medical equipment or furnishing negative pressure wound therapy using a disposable device.

- Remove § 484.210 which discusses data used for the calculation of the national prospective 60-day episode payment as we believe that this information is incorporated in other sections of part 484 subpart E, such as § 484.205(c), § 484.215(a) and (b), § 484.220 and § 484.215.

- Revise the section heading of § 484.215 from “Initial establishment of the calculation of the national 60-day episode payment” to “Initial establishment of the calculation of the national, standardized prospective 60-day episode payment and 30-day payment rates.” Also, we propose to add paragraph (f) to this section to describe how the national, standardized prospective 60-day episode payment rate is converted into a national, standardized prospective 30-day period payment and when it applies.

- Revise the section heading of § 484.220 from “Calculation of the adjusted national prospective 60-day episode payment rate for case-mix and area wage levels” to “Calculation of the case-mix and wage area adjusted prospective payment rates.” We propose to remove the reference to “national 60-day episode payment rate” and replace it with “national, standardized prospective payment”.

- Revise the section heading in § 484.225 from “Annual update of the unadjusted national prospective 60-day episode payment rate” to “Annual update of the unadjusted national, standardized prospective 60-day

episode and 30-day payment rates”. Also, we propose to revise § 484.225 to remove references to “60-day episode” and to refer more generally to the “national, standardized prospective payment”. In addition, we propose to add paragraph (d) to describe the annual update for CY 2019.

- Revise the section heading of § 484.230 from “Methodology used for the calculation of low-utilization payment adjustment” to “Low utilization payment adjustment”. Also, we propose to designate the current text to paragraph (a) and insert language such that proposed paragraph (a) applies to episodes beginning on or before December 31, 2018, using the current payment system. We propose to add paragraph (b) to describe how low utilization payment adjustments are determined for periods beginning on or after January 1, 2019, using the proposed HHGM.

- Revise the section heading of § 484.235 from “Methodology used for the calculation of partial episode payment adjustments” to “Partial payment adjustments”. We propose to remove paragraphs (a), (b), and (c). We propose to remove paragraphs (1), (2), and (3) which describe partial payment adjustments from paragraph (d) in § 484.205 and incorporate them into § 484.235. We propose to add paragraph (a) to describe partial payment adjustments under the current system, that is, for episodes beginning on or before December 31, 2018, and paragraph (b) to describe partial payment adjustments under the proposed HHGM, that is, for periods beginning on or after January 1, 2019.

- Revise the section heading for § 484.240 from “Methodology used for the calculation of the outlier payment” to “Outlier payments.” In addition, we propose to remove language at paragraph (b) and append it to paragraph (a). We propose to add language to proposed revised paragraph (a) such that paragraph (a) will apply to payments under the current system, that is, for episodes beginning on or before December 31, 2018. We propose to revise paragraph (b) to describe payments under the proposed HHGM, that is, for periods beginning on or after January 1, 2019. In paragraph (c), we propose to replace the “estimated” cost with “imputed” cost. Lastly, we propose to revise paragraph (d) to reflect the per-15 minute unit approach to imputing the cost for each claim.

We are soliciting comments on the proposed HHGM as outlined in sections III.E.1. through III.E.12. and the associated regulations text changes

described above and in the regulations text of this proposed rule.

IV. Proposed Provisions of the Home Health Value-Based Purchasing (HHVBP) Model

A. Background

As authorized by section 1115A of the Act and finalized in the CY 2016 HH PPS final rule (80 FR 68624), we began testing the HHVBP Model on January 1, 2016. The HHVBP Model has an overall purpose of improving the quality and delivery of home health care services to Medicare beneficiaries. The specific goals of the Model are to: (1) Provide incentives for better quality care with greater efficiency; (2) study new potential quality and efficiency measures for appropriateness in the home health setting; and (3) enhance the current public reporting process.

Using the randomized selection methodology finalized in the CY 2016 HH PPS final rule, nine states were selected for inclusion in the HHVBP Model, representing each geographic area across the nation. All Medicare-certified HHAs providing services in Arizona, Florida, Iowa, Maryland, Massachusetts, Nebraska, North Carolina, Tennessee, and Washington (competing HHAs) are required to compete in the Model. Requiring all Medicare-certified HHAs providing services in the selected states to participate in the Model ensures that: (1) there is no selection bias; (2) participating HHAs are representative of HHAs nationally; and, (3) there is sufficient participation to generate meaningful results.

As finalized in the CY 2016 HH PPS final rule, the HHVBP Model will utilize the waiver authority under section 1115A(d)(1) of the Act to adjust Medicare payment rates under section 1895(b) of the Act beginning in CY 2018 based on performance on applicable measures. Payment adjustments will be increased incrementally over the course of the HHVBP Model in the following manner: (1) A maximum payment adjustment of 3 percent (upward or downward) in CY 2018; (2) a maximum payment adjustment of 5 percent (upward or downward) in CY 2019; (3) a maximum payment adjustment of 6 percent (upward or downward) in CY 2020; (4) a maximum payment adjustment of 7 percent (upward or downward) in CY 2021; and (5) a maximum payment adjustment of 8 percent (upward or downward) in CY 2022. Payment adjustments will be based on each HHA’s Total Performance Score (TPS) in a given performance year (PY) on (1) a set of measures already

reported via OASIS and HHCAHPS for all patients serviced by the HHA and select claims data elements, and (2) three New Measures where points are achieved for reporting data.

As finalized in the CY 2017 HH PPS final rule (81 FR 76741 through 76752), in addition to providing an update on the progress towards developing public reporting of performance under the HHVBP Model, we finalized the following changes related to the HHVBP Model:

- Calculating benchmarks and achievement thresholds at the state level rather than the level of the size-cohort and revising the definition for benchmark to state that benchmark refers to the mean of the top decile of Medicare-certified HHA performance on the specified quality measure during the baseline period, calculated for each state;

- Requiring a minimum of eight HHAs in a size-cohort;

- Increasing the timeframe for submitting New Measure data from seven calendar days to 15 calendar days following the end of each reporting period to account for weekends and holidays;

- Removing four measures (Care Management: Types and Sources of Assistance, Prior Functioning Activities of Daily Living (ADL)/Instrumental ADL (IADL), Influenza Vaccine Data Collection Period, and Reason Pneumococcal Vaccine Not Received) from the set of applicable measures;

- Adjusting the reporting period and submission date for the Influenza Vaccination Coverage for Home Health Personnel measure from a quarterly submission to an annual submission; and

- Allowing for an appeals process that includes the recalculation process finalized in the CY 2016 HH PPS final rule (80 FR 68688 through 68689), as modified, and adds a reconsideration process.

B. Quality Measures

1. Proposed Adjustment to the Minimum Number of Completed Home Health Care Consumer Assessment of Healthcare Providers and System (HHCAHPS) Surveys

The HHCAHPS survey presents home health patients with a set of standardized questions about their home health care providers and about the quality of their home health care. The survey is designed to measure the experiences of people receiving home health care from Medicare-certified home health care agencies and meet the following three broad goals to: (1)

Produce comparable data on the patient's perspective that allows objective and meaningful comparisons between home health agencies on domains that are important to consumers; (2) create incentives through public reporting of survey results for agencies to improve their quality of care; and (3) enhance public accountability in health care by increasing the transparency of the quality of care provided in return for public investment through public reporting.

As finalized in the CY 2016 HH PPS final rule (80 FR 68685 through 68686), if a HHA does not have a minimum of 20 episodes of care during a performance year to generate a performance score on at least five measures, that HHA would not be included in the Linear Exchange Function (LEF) and would not have a payment adjustment percentage calculated. The LEF is used to translate an HHA's Total Performance Score (TPS) into a percentage of the value-based payment adjustment earned by each HHA under the HHVBP Model. For the HHCAHPS measures, a minimum of 20 HHCAHPS completed surveys would be necessary in order for scores to be generated for the HHCAHPS quality measures that can be included in the calculation of the TPS.

We believe, however, that using a minimum of 40 completed HHCAHPS surveys, rather than a minimum of 20 completed HHCAHPS surveys, would better align the Model with HHCAHPS policy for the Patient Survey Star Ratings on Home Health Compare.¹⁰⁰ The decision to use a minimum of 40 completed surveys for these star ratings was a result of balancing two competing goals. One goal was to provide star ratings that were meaningful and minimized random variations. This goal was best served by calculating star ratings for large numbers of cases by having a larger minimum of completed HHCAHPS surveys (for example, 50 or 100 completed HHCAHPS surveys). At the same time, we also wanted to be able to provide star ratings for as many HHAs as possible. This goal was best served by using a lower minimum of completed HHCAHPS surveys (for example, 20 completed HHCAHPS surveys). We chose to balance these opposing and necessary goals by using 40 completed HHCAHPS surveys for the Patient Survey Star Ratings. Because we believe that aligning the Patient Survey Star Ratings system and the HHVBP

model provides uniformity, consistency, and standard transformability for different healthcare platforms, we therefore propose using a minimum of 40 instead of 20 completed HHCAHPS surveys under the HHVBP.

We note that we received a comment in response to the CY 2016 HH PPS proposed rule in support of using a higher minimum threshold for HHCAHPS completed surveys for the Patient Survey Star Ratings if the data are going to be used in HHVBP or any other quality assessment program (80 FR 68709). We also note that we received public comment in response to the CY 2017 HH PPS proposed rule in support of using a higher minimum threshold for HHCAHPS completed surveys in the HHVBP Model, including a recommendation to use a minimum of 100 HHCAHPS rather than a sample size of 20 surveys (81 FR 76747). We believe that proposing a minimum of 40 completed HHCAHPS surveys for the Model would be more appropriate than the higher minimums previously recommended by some commenters because it represents a balance between providing meaningful data and having sufficient numbers of HHAs with performance scores for at least 5 measures in the cohorts. Moreover, as we noted, it aligns with the Patient Survey Star Ratings on Home Health Compare.

To understand the possible impact of our proposal to use a minimum of 40 HHCAHPS completed surveys, we note that HHAs may refer to the Interim Performance Reports (IPRs) issued in October 2016, January 2017 and April 2017, which analyzed 40 or more completed HHCAHPS surveys across both small and large cohorts in determining each HHA's HHCAHPS quality measure scores. As a point of comparison to the minimum of 40 HHCAHPS completed surveys, we note that these IPRs will be reissued using 20 or more completed HHCAHPS surveys and include quality measure scores, for these same time periods, calculated with HHAs that qualify for the LEF by having sufficient data for at least five measures. HHAs will have the opportunity to submit a request for recalculation of the revised interim performance scores.

HHAs have an opportunity to evaluate these IPRs in light of our proposal to change to a minimum of 40 HHCAHPS completed surveys, as well as seek clarification on the difference in their reports. The participating HHAs will receive concurrent IPRs in July 2017 and concurrent Annual Total Performance Score and Payment Adjustment Reports, which we plan to

make available in the last week of August 2017. The concurrent reports will show one report with HHCAHPS quality measure scores calculated based on a minimum of 40 completed surveys and one report with HHCAHPS quality measure scores calculated based on a minimum of 20 completed surveys. Because this proposed rule will not be finalized before the timeline for submission of recalculation and reconsideration requests, HHAs will have the opportunity to submit recalculation requests for the interim performance scores based on both a minimum of 40 and 20 completed surveys, and recalculation and reconsideration requests, as applicable, for the annual total performance scores included in these reports for these thresholds in accordance with the appeals process set forth at § 484.335, which was finalized in the CY 2017 HH PPS final rule.

We analyzed the effects on participating HHAs of using the proposed 40 or more completed HHCAHPS surveys as compared to using 20 or more completed HHCAHPS surveys by examining OASIS measures submitted from January 1, 2015 through December 31, 2016, claims measures submitted from September 1, 2015 through September 30, 2016, and 12 months ending June 30, 2016 for HHCAHPS-based measures. We also found that achievement thresholds, which are calculated as the median of all HHAs' performance on the specified quality measures during the 2015 baseline year for each state, would not change by more than ± 1.1 percent, with the largest changes occurring in the statewide achievement thresholds for the HHCAHPS *Willingness to Recommend the Agency* measure in Arizona (+1.1 percent) and Nebraska (−1.1 percent). Benchmarks (the mean of the top decile of Medicare-certified HHA performance on the specified quality measures during the 2015 baseline year, calculated for each state) had greater potential for change, ranging down to −3.2 percent. For instance, we found that when calculated using a minimum of 40 surveys rather than a minimum of 20 surveys, there was a −2.0 percent reduction in the benchmark for the HHCAHPS *Willingness to Recommend the Agency* measure for Arizona and a −1.7 percent reduction in the benchmark for Nebraska. We also found that when calculated using a minimum of 40 surveys rather than a minimum of 20 surveys, there was a −1.7 percent reduction in the benchmark for the HHCAHPS *Communications between*

¹⁰⁰ Patient Survey Star Ratings <https://www.medicare.gov/HomeHealthCompare/Data/Patient-Survey-Star-Ratings.html>.

Providers and Patients measure for Arizona, a –1.7 percent reduction in the benchmark for Florida, and a –3.2 percent reduction in the benchmark for Nebraska.

Overall, the proposed change in the HHCAHPS minimum of 40 completed surveys is estimated to result in a limited percent change in the average statewide TPS for larger-volume HHAs, ranging from –0.4 through +2.2 percent. Because the underlying data does not cover the full 2016 calendar year, the data limitation may impact the final total performance scores and corresponding payment adjustment percentages. We provide estimates of the expected payment adjustment distribution based on the proposed minimum of 40 completed HHCAHPS surveys in the impact analysis of this proposed rule.

We are inviting public comments on our proposal to use 40 or more completed HHCAHPS surveys as the minimum to generate a quality measure score on the HHCAHPS measures, as is currently used in Home Health Compare and the Patient Survey Star Ratings. Therefore, we propose to revise the definition of “applicable measure” at § 484.305 to reflect this proposal, from a measure for which the competing HHA has provided 20 home health episodes of care per year to a measure for which a competing HHA has provided a minimum of 20 home health episodes of care per year for the OASIS-based measures, 20 home health episodes of care per year for the claims-based measures, or 40 completed surveys for the HHCAHPS measures. This proposal, if finalized, would apply to the calculation of the benchmark and achievement thresholds and the calculation of performance scores for all Model years, beginning with Performance Year (PY) One.

2. Proposal To Remove One OASIS-Based Measure Beginning With Performance Year 3

In the CY 2016 HH PPS final rule, we finalized a set of quality measures in Figure 4a: Final PY1 Measures and Figure 4b: Final PY1 New Measures (80 FR 68671 through 68673) for the HHVBP Model to be used in the first performance year (PY1), referred to as the starter set.

The measures were selected for the Model using the following guiding principles: (1) Use a broad measure set that captures the complexity of the

services HHAs provide; (2) Incorporate the flexibility for future inclusion of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT) measures that cut across post-acute care settings; (3) Develop ‘second generation’ (of the HHVBP Model) measures of patient outcomes, health and functional status, shared decision making, and patient activation; (4) Include a balance of process, outcome and patient experience measures; (5) Advance the ability to measure cost and value; (6) Add measures for appropriateness or overuse; and (7) Promote infrastructure investments. This set of quality measures encompasses the multiple National Quality Strategy (NQS) domains¹⁰¹ (80 FR 68668). The NQS domains include six priority areas identified in the CY 2016 HH PPS final rule (80 FR 68668) as the CMS Framework for Quality Measurement Mapping. These areas are: (1) Clinical quality of care; (2) Care coordination; (3) Population & community health; (4) Person- and Caregiver-centered experience and outcomes; (5) Safety; and (6) Efficiency and cost reduction. Figures 4a and 4b of the CY 2016 HH PPS final rule identified 15 outcome measures (five from the HHCAHPS, eight from Outcome and Assessment Information Set (OASIS), and two from the Chronic Care Warehouse (claims)), and nine process measures (six from OASIS, and three New Measures, which were not previously reported in the home health setting).

In the CY 2017 HH PPS final rule, we removed the following four measures from the measure set for PY 1 and subsequent performance years: (1) Care Management: Types and Sources of Assistance; (2) Prior Functioning ADL/IADL; (3) Influenza Vaccine Data Collection Period: Does this episode of care include any dates on or between October 1 and March 31?; and (4) Reason Pneumococcal Vaccine Not Received, for the reasons discussed in that final rule (81 FR 76743 through 76747).

For Performance Year 3 (PY 3), we are proposing to remove one OASIS-based measure, Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care, from the set of applicable measures. As part of our ongoing monitoring efforts,

we found that based on the standard metrics of measure performance, many providers have achieved full performance on the Drug Education measure. For example, for the January 2017 IPRs (which covered the 12-month period of October 1, 2015 through September 30, 2016), the average value for this measure across all participating HHAs was 95.69 percent from October 2015 through September 2016. When looking at just September 2016, the mean value on this measure across all participating HHAs had increased to 97.8 percent. Also, there are few HHAs with poor performance on the measure. Based on the January 2017 IPRs, across all participating HHAs, the 10th percentile was 89 percent and the 5th percentile was 81.8 percent, but only 1.8 percent of HHAs had a value below 70 percent on the measure. We believe that removing this measure would be consistent with our policy, as noted in the CY 2017 HH PPS final rule (81 FR 76746), that when a measure has achieved full performance, we may propose the removal of the measure in future rulemaking. In addition, our contractor’s Technical Expert Panel (TEP), which consists of 11 panelists with expertise in home health care and quality measures, expressed concern that the Drug Education measure does not capture whether the education provided by the HHA was meaningful.

The revised set of applicable measures, if our proposal to remove the OASIS-based measure, Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care, is finalized, is presented in Table 43. This measure set would be applicable to PY3 and each subsequent performance year until such time that another set of applicable measures, or changes to this measure set, are proposed and finalized in future rulemaking.

¹⁰² For more detailed information on the proposed measures utilizing OASIS refer to the *OASIS-C1/ICD-9, Changed Items & Data Collection Resources* dated September 3, 2014 available at www.oasisanswers.com/LiteratureRetrieve.aspx?ID=215074.

For NQF endorsed measures see The NQF Quality Positioning System available at <http://www.qualityforum.org/QPS>. For non-NQF measures using OASIS see links for data tables related to OASIS measures at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html>. For information on HHCAHPS measures see <https://homehealthcahps.org/SurveyandProtocols/SurveyMaterials.aspx>.

¹⁰¹ 2015 Annual Report to Congress, <http://www.aahrq.gov/workingforquality/reports/annual-reports/nqs2015annlrpt.htm>.

TABLE 43—MEASURE SET FOR THE HHVBP MODEL ¹⁰² BEGINNING PY 3

NQS domains	Measure title	Measure type	Identifier	Data source	Numerator	Denominator
Clinical Quality of Care.	Improvement in Ambulation-Locomotion.	Outcome	NQF0167	OASIS (M1860).	Number of home health episodes of care where the value recorded on the discharge assessment indicates less impairment in ambulation/locomotion at discharge than at the start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.
Clinical Quality of Care.	Improvement in Bed Transferring.	Outcome	NQF0175	OASIS (M1850).	Number of home health episodes of care where the value recorded on the discharge assessment indicates less impairment in bed transferring at discharge than at the start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.
Clinical Quality of Care.	Improvement in Bathing.	Outcome	NQF0174	OASIS (M1830).	Number of home health episodes of care where the value recorded on the discharge assessment indicates less impairment in bathing at discharge than at the start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.
Clinical Quality of Care.	Improvement in Dyspnea.	Outcome	NA	OASIS (M1400).	Number of home health episodes of care where the discharge assessment indicates less dyspnea at discharge than at start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.
Communication & Care Coordination.	Discharged to Community.	Outcome	NA	OASIS (M2420).	Number of home health episodes where the assessment completed at the discharge indicates the patient remained in the community after discharge.	Number of home health episodes of care ending with discharge or transfer to inpatient facility during the reporting period, other than those covered by generic or measure-specific exclusions.
Efficiency & Cost Reduction.	Acute Care Hospitalization: Unplanned Hospitalization during first 60 days of Home Health.	Outcome	NQF0171	CCW (Claims).	Number of home health stays for patients who have a Medicare claim for an unplanned admission to an acute care hospital in the 60 days following the start of the home health stay.	Number of home health stays that begin during the 12-month observation period. A home health stay is a sequence of home health payment episodes separated from other home health payment episodes by at least 60 days.
Efficiency & Cost Reduction.	Emergency Department Use without Hospitalization.	Outcome	NQF0173	CCW (Claims).	Number of home health stays for patients who have a Medicare claim for outpatient emergency department use and no claims for acute care hospitalization in the 60 days following the start of the home health stay.	Number of home health stays that begin during the 12-month observation period. A home health stay is a sequence of home health payment episodes separated from other home health payment episodes by at least 60 days.
Patient Safety	Improvement in Pain Interfering with Activity.	Outcome	NQF0177	OASIS (M1242).	Number of home health episodes of care where the value recorded on the discharge assessment indicates less frequent pain at discharge than at the start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.
Patient Safety	Improvement in Management of Oral Medications.	Outcome	NQF0176	OASIS (M2020).	Number of home health episodes of care where the value recorded on the discharge assessment indicates less impairment in taking oral medications correctly at discharge than at start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.
Population/Community Health.	Influenza Immunization Received for Current Flu Season.	Process	NQF0522	OASIS (M1046).	Number of home health episodes during which patients (a) received vaccination from the HHA or (b) had received vaccination from HHA during earlier episode of care, or (c) was determined to have received vaccination from another provider.	Number of home health episodes of care ending with discharge, or transfer to inpatient facility during the reporting period, other than those covered by generic or measure-specific exclusions.
Population/Community Health.	Pneumococcal Polysaccharide Vaccine Ever Received.	Process	NQF0525	OASIS (M1051).	Number of home health episodes during which patients were determined to have ever received Pneumococcal Polysaccharide Vaccine (PPV).	Number of home health episodes of care ending with discharge or transfer to inpatient facility during the reporting period, other than those covered by generic or measure-specific exclusions.
Patient & Care-giver-Centered Experience.	Care of Patients ..	Outcome		CAHPS	NA	NA.
Patient & Care-giver-Centered Experience.	Communications between Providers and Patients.	Outcome		CAHPS	NA	NA.

TABLE 43—MEASURE SET FOR THE HHVBP MODEL ¹⁰² BEGINNING PY 3—Continued

NQS domains	Measure title	Measure type	Identifier	Data source	Numerator	Denominator
Patient & Care-giver-Centered Experience.	Specific Care Issues.	Outcome		CAHPS	NA	NA.
Patient & Care-giver-Centered Experience.	Overall rating of home health care.	Outcome		CAHPS	NA	NA.
Patient & Care-giver-Centered Experience.	Willingness to recommend the agency.	Outcome		CAHPS	NA	NA.
Population/Community Health.	Influenza Vaccination Coverage for Home Health Care Personnel.	Process	NQF0431 (Used in other care settings, not Home Health).	Reported by HHAs through Web Portal.	Healthcare personnel in the denominator population who during the time from October 1 (or when the vaccine became available) through March 31 of the following year: (a) Received an influenza vaccination administered at the healthcare facility, or reported in writing or provided documentation that influenza vaccination was received elsewhere; or (b) were determined to have a medical contraindication/condition of severe allergic reaction to eggs or to other components of the vaccine or history of Guillain-Barre Syndrome within 6 weeks after a previous influenza vaccination; or (c) declined influenza vaccination; or (d) persons with unknown vaccination status or who do not otherwise meet any of the definitions of the above-mentioned numerator categories.	Number of healthcare personnel who are working in the healthcare facility for at least 1 working day between October 1 and March 31 of the following year, regardless of clinical responsibility or patient contact.
Population/Community Health.	Herpes zoster (Shingles) vaccination: Has the patient ever received the shingles vaccination?	Process	NA	Reported by HHAs through Web Portal.	Total number of Medicare beneficiaries aged 60 years and over who report having ever received zoster vaccine (shingles vaccine).	Total number of Medicare beneficiaries aged 60 years and over receiving services from the HHA.
Communication & Care Coordination.	Advance Care Plan.	Process	NQF0326	Reported by HHAs through Web Portal.	Patients who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advanced care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	All patients aged 65 years and older.

We invite public comment on the proposal to remove one OASIS-based measure, Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care, from the set of applicable measures for PY3 and subsequent performance years and Table 43.

C. Quality Measures for Future Consideration

The CY 2016 HH PPS final rule discusses the HHVBP Model design, the guiding principles to select measures, and the six priority areas of the National Quality Strategy (NQS) we considered for the Model (80 FR 68656 through 68678). Under the HHVBP Model, any measures we determine to be good indicators of quality will be considered for use in the HHVBP Model in future years, and may be added or removed through the rulemaking process. To

further our commitment to objectively assess HHVBP quality measures, we are utilizing an implementation contractor that invited a group of measure experts to provide advice on the adjustment of the current measure set for consideration. The contractor convened a technical expert panel (TEP) consisting of 11 panelists with expertise in home health care and quality measures that met on September 7, 2016, in Baltimore, Maryland and via conference call on December 2, 2016. The TEP discussed developing a composite total change in ADL/IADL measure; a composite functional decline measure; a measure to capture when an HHA correctly identifies the patient's need for mental and behavioral health supervision; and a measure to identify if a caregiver is able to provide the patient's mental or behavioral health supervision, to align with

§ 409.45(b)(3)(iii) and the Medicare Benefit Policy Manual (Pub. 100–02), Chapter 7, Section 20.2. We discuss each of these potential measures in further detail in this section of the proposed rule. While any new measures would be proposed for use in future rulemaking, we are inviting comment on these potential measures now to inform measure development and selection.

As noted in the CY 2017 HH PPS final rule (81 FR 76747), we received several comments expressing concern that the measures under the Model do not reflect the patient population served under the Medicare Home Health benefit as the outcome measures focus on a patient's clinical improvement and do not address patients with chronic illnesses; deteriorating neurological, pulmonary, cardiac, and other conditions; and some with terminal illness. These commenters opined that the value of

including stabilization measures in the HHVBP Model is readily apparent as it aligns the Model with the Medicare Home Health benefit. Commenters also expressed concerns that improvement is not always the goal for each patient and that stabilization is a reasonable clinical goal for some patients. Commenters suggested the addition of stabilization or maintenance measures be considered for the HHVBP Model. Many commenters objected to the use of improvement measures in the HHVBP Model. We did not receive any specific measures for future consideration. In the subsections that follow, we are identifying measures that we are considering for possible inclusion under the Model in future rulemaking and are seeking input from the public on the measures mentioned, as well as any input about the development or construction of the measures and their features or methodologies.

1. Total Change in ADL/IADL Performance by HHA Patients

The measure set finalized in the CY 2016 HH PPS final rule included Change in Daily Activity Function as Measured by the Activity Measure for Post-Acute Care (AM-PAC) (NQF #0430). However, the measure was removed in the CY 2017 HH PPS final rule and never used in the HHVBP Model because the measure required use of a proprietary data collection instrument in the home health environment. We are considering replacing Change in Daily Activity Function as Measured by AM-PAC (NQF #0430) with a composite total ADL/IADL change performance measure. During the September 2016 TEP meeting, an alternative to the Change in Daily Activity Function measure was presented. The TEP requested that a composite Total ADL/IADL Change measure be investigated empirically. This measure was discussed as part of the follow-up conference call, and the TEP supported continued development of the measure in the HHVBP Model as a way of including a measure that captures all three potential outcomes for home health patients: Stabilization; decline; and improvement. They provided input on the technical specifications of the potential composite measure, including the feasibility of implementing the measure and the overall measure reliability and validity. We have reviewed this suggested alternative and

believe this measure would provide actionable and transparent information that would support HHA efforts to improve care and prevent functional decline for all patients across a broad range of patient functional outcomes. The measure would also improve accountability during an episode of care when the patient is directly under the HHA's care.

The name of this potential composite measure could be *Total Change in ADL/IADL Performance by HHA Patients*. The measure would report the average, normalized, total improved functioning across the 11 ADL/IADL items on the current OASIS-C2 instrument. The measure is calculated by comparing scores from the start-of-care/resumption of care to scores at discharge. For each item the patient's discharge assessed performance score is subtracted from the patient's start of care/resumption of care assessed performance score, and then divided by the maximum improvement value based on the number of response options for that item. These values are summed into a total normalized change score that can range from -11 (that is, for an episode where there is maximum decline on all 11 items used in the measure) to +11 (that is, for an episode where there is the maximum improvement on all 11 items). An HHA's score on the measure is based on its average across all eligible episodes. Patients who are independent on all 11 ADL/IADL items at Start of Care (SOC)/Resumption of Care (ROC) would also be included in the measure. The HHA's observed score on the measure is the average of the normalized total scores for all eligible episodes for its patients during the reporting period.

The following 11 ADLs/IADL-related items from OASIS-C2 items were included in developing a composite measure:

ADL OASIS-C2 items related to Self-Care:

- M1800 (Grooming).
- M1810 (Upper body dressing).
- M1820 (Lower body dressing).
- M1845 (Toileting hygiene).
- M1870 (Eating).

ADL OASIS-C2 items related to Mobility:

- M1840 (Toilet transferring).
- M1840 (Bed transferring).
- M1860 (Ambulation).

Other IADLs OASIS items:

- M1880 (Light meal preparation).
- M1890 (Telephone use).

- M2020 (Oral medication management).

Based on the measures identified above, we would risk-adjust using OASIS-C2 items to account for case-mix variation and other factors that affect functional decline but are beyond the influence of the HHA. The risk-adjustment model uses an ordinary least squares (OLS)^{103 104} regression framework because the outcome measure (normalized change in ADL/IADL performance) is a continuous variable.

The prediction model for this outcome measure was derived using the predicted values from the 11 individual outcomes that are currently used to risk adjust these 11 individual quality measures. Of the 11 values tested, the 8 identified in this proposed rule were found to be statistically related to the *Total Change in ADL/IADL Performance by HHA Patients* measure at $p < 0.0001$ level and would be used in the prediction model that we are considering proposing to use to risk adjust the HHA's observed value with respect to this potential future measure. The prediction model for this outcome measure uses predicted values from the following individual outcomes (*Note:* The primary source OASIS item is listed in parenthesis after the name of the quality measure):

- Improvement in Upper Body Dressing (M1810).
- Improvement in Management of Oral Medications (M2020).
- Improvement in Bed Transferring (M1850).
- Improvement in Ambulation/ Locomotion (M1860).
- Improvement in Grooming (M1800).
- Improvement in Toileting Hygiene (M1845).
- Discharged to the Community (M2420).
- Improvement in Toileting Transfer (M1840).

Two predictive models, one based on predicted values from CY2014 and one from CY2015, were computed. The correlations at the episode level between observed and predicted values for the target outcome measure *Total Change in ADL/IADL Performance by HHA Patients* are shown in Table 44.

¹⁰³ Fox, John (1997). *Applied Regression Analysis, Linear Models, and Related Methods*/ Edition 1, 1997, SAGE.

¹⁰⁴ Green, William H. (2017). *Econometric analysis* (8th ed.). New Jersey: Pearson. ISBN 978-0134461366.

TABLE 44—CORRELATIONS AT THE EPISODE LEVEL BETWEEN OBSERVED AND PREDICTED VALUES FOR THE TARGET OUTCOME MEASURE TOTAL CHANGE IN ADL/IADL PERFORMANCE BY HHA PATIENTS

Data group	Correlation	Significance (p <)	r ² (Coeff. Determination) (%)
CY2014, National	0.5022	0.0001	25.22
CY2014, HHVBP states	0.5094	0.0001	25.95
CY2015, National	0.5011	0.0001	25.11
CY2015, HHVBP states	0.5076	0.0001	25.76

The results in Table 44 suggest that either model would account for 25 percent or more of the variability in the outcome measure. These models could be considered very strong predictive models for the target outcome measure. Although the analysis supports developing a composite measure, the analysis assumes that the OASIS–C2 items identified to be used in the composite measure do not change; however, we recognize that OASIS–C2 items could be removed or added in any given year. We expect to conduct an additional analysis, in advance of any future proposal, to assess whether changes to OASIS–C2 items that are removed or added could significantly impact a HHA's ability to address several measures to improve its overall score in the composite measure. We are soliciting public comments on whether or not to include a composite total ADL/IADL change performance measure in the set of applicable measures, the name of any such measure, the risk adjustment method, and whether we should conduct an analysis of the impact of removal/addition of OASIS–C2 items.

2. Composite Functional Decline Measure

The second measure we are considering for possible inclusion under the Model in future rulemaking is a *Composite Functional Decline Measure* that could be the percentage of episodes where there was decline on one or more of the eight ADL items used in the measure. As noted in this proposed rule, we received comments on the CY 2017 HH PPS proposed rule suggesting that we consider the addition of stabilization or maintenance measures. To address this suggestion, we are considering a composite functional decline measure because the existing functional stabilization measures, taken individually, are topped out, with HHA level means of 95 percent or higher. This type of composite functional decline measure is similar to the composite ADL decline measure that is used in the Skilled Nursing Facility

(SNF) Quality Reporting program (QRP).¹⁰⁵ The SNF QRP measure is constructed from four ADL items: Bed mobility; transfer; eating; and toileting.

An HHVBP composite functional decline measure could provide actionable and transparent information that could support HHA efforts to improve care and prevent functional decline for all patients, including those for whom improvement in functional status is not a realistic care goal. This concept was discussed during the TEP meeting on September 7, 2016, with a follow-up conference call held on December 2, 2016. The TEP supported the inclusion of measures of stabilization and decline in the HHVBP Model, as well as further development of the composite functional decline measure. They provided input on the technical specifications of the potential composite measure, including the feasibility of implementing the measure and the overall measure reliability and validity.

When calculating the composite functional decline measure, we could use the following 8 existing OASIS–C2 items identified below:

- Ambulation/Locomotion (M1860).
- Bed Transferring (M1840).
- Toilet Transferring (M1840).
- Bathing (M1830).
- Toilet Hygiene (M1845).
- Lower Body Dressing (M1820).
- Upper Body Dressing (M1810).
- Grooming (M1800).

The measure could be defined as 1 if there is decline reported in one or more of these items between the Start of Care and the Discharge assessments and zero if no decline is reported on any of these items. As with other OASIS-based measures, a performance score for the measure would only be calculated for HHAs that have 20 or more episodes of care during a performance year.

The measure could be risk-adjusted using OASIS–C2 items to account for

case-mix variation and other factors that affect functional decline but are beyond the influence of the HHA. The risk-adjustment model uses a logistic regression framework. The model includes a large number of patient clinical conditions and other characteristics measured at start of care. A logistic regression model is estimated to predict whether the patient will have length of stay of greater than 60 days. The predicted probability of length of stay of greater than 60 days is used, along with other patient characteristics, to construct a logistic regression model to predict the probability of decline in any of eight ADLs. This model is used to estimate the predicted percent of ADL decline at the HHA level. To calculate case-mix adjusted values, the observed value of the measure is adjusted by the difference between the HHA predicted percent and the national predicted percent. The risk-adjustment model reduces the adjusted difference between HHAs that serve a disproportionate number of longer-stay patients and those that serve patients with more typical lengths of stay of one episode.

Across all participating HHAs in the HHVBP Model, for HHAs that had less than 20 percent of episodes lasting more than 60 days, the average on the functional decline measure was 8.08 percent. This increased to 11.08 percent for HHAs with 20 percent to 40 percent of episodes lasting more than 60 days, 14.23 percent for HHAs with 40 percent to 60 percent of episodes lasting more than 60 days, and 20.59 percent for HHAs with more than 60 percent of episodes lasting more than 60 days. This finding suggests that, in addition to focusing on prevention of functional decline, we should also attempt to better predict a patient's functional trajectory and potentially stratify the population to exclude those on a likely downward trajectory. However, in spite of this finding, the inclusion of a measure that rewards providers for avoiding functional decline has the advantage of diversifying the set of measures for the HHVBP model. We are soliciting public comments on whether or not to include

¹⁰⁵ “Long-stay Nursing Home Care: Percent of Residents Whose Need for help with Activities of Daily Living has Increased.” <https://www.qualitymeasures.ahrq.gov/summaries/summary/50060>.

a composite functional decline measure in the set of applicable measures, the name of any such measure, the risk adjustment method, and whether we should conduct an analysis of the impact of removal/addition of OASIS–C2 items.

3. Behavioral Health Measures

Although we did not receive comments or suggestions through the rulemaking process for the HHVBP Model regarding behavioral or mental health measures, we recognize that the Model does not include such measures. The OASIS–C2 collects several items related to behavioral and mental health (M1700 Cognitive Functioning; M1710 Confusion Frequency; M1720 Anxiety; M1730 Depression Screening; M1740 Cognitive, Behavioral, and Psychiatric Symptoms; M1745 Frequency of Disruptive Behavior Symptoms; and M1750 Psychiatric Nursing Services). These items are used to compute both Improvement and Process measures as well as Potentially Avoidable Events. The inclusion of behavioral health measures is important for care transformation and improvement activities as many persons served by the Home Health program may have behavioral health needs.

The TEP made several suggestions during the December 2016 conference call as to whether the focus of a behavioral or mental health measure could be identifying whether a patient needed mental or behavioral health assistance compared to the supervision of the patient or advocacy assistance. The TEP supports the supervision type measure due to its opportunity for potential improvement. In further analyses, we identified two underlying components to outcomes for providing assistance. We developed a method, described below, to identify patients who have or do not have needs for mental or behavioral health supervision. We are considering further refining this method by identifying the involvement of the caregiver in addressing the patient's mental or behavioral health supervision needs as an important outcome measure, and we seek comment on whether this is an appropriate factor or feature that we should consider in developing such a measure in future rulemaking.

a. HHA Correctly Identifies Patient's Need for Mental or Behavioral Health Supervision

We are considering adding a *HHA Correctly Identifies Patient's Need for Mental or Behavioral Health Supervision* measure to the HHVBP Model in the future to capture a

patient's need for mental or behavioral health supervision based on an identifier. This identifier is based on information from existing Neuro/Emotional/Behavioral Status OASIS items, along with other indicators of mental/behavioral health problems to identify a patient in need of supervisory assistance. The outcome measure assesses whether the HHA correctly identifies whether or not the patient needs mental or behavioral health supervision based on the OASIS SOC/ROC assessment item M2102f, Types and Sources of Assistance: Supervision and Safety.

A composite Mental/Behavioral Health measure could be a dichotomous measure that reports the percentage of episodes of care where the HHA correctly identifies: (a) Patients who need mental or behavioral health supervision; and (b) patients who don't need mental or behavioral health supervision. The numerator could be a combination of two values: (1) The number of episodes of care where the HHA correctly identifies patients who need mental or behavioral health supervision; plus (2) the number of episodes of care where the HHA correctly identifies patients who don't need mental or behavioral health supervision. The denominator is all episodes of care.

The composite measure requires that a patient's need for mental or behavioral health supervision be identified. The following algorithm was designed to identify if a patient was in need of mental or behavioral health supervision. If the patient met any of the following conditions, the patient was identified by the algorithm as in need of mental or behavioral health supervision:

- Was discharged from a psychiatric hospital prior to entering home health care (M1000 = 6);
- Is diagnosed as having chronic mental behavioral problems (M1021 and M1023);
- Is diagnosed with a mental illness (M1021 and M1023);
- Is cognitively impaired (M1700 > = 2);
- Is confused (M1710 > = 2);
- Is identified as having a memory deficit (M1740 = 1);
- Is identified as having impaired decision-making (M1740 = 2);
- Is identified as being verbally disruptive (M1740 = 3);
- Is identified as being physically aggressive (M1740 = 4);
- Is identified as exhibiting disruptive, infantile, or inappropriate behaviors (M1740 = 5);
- Is identified as being delusional (M1740 = 6); or

- Has a frequency of disruptive symptoms (M1745 >= 2).

The measure also requires that the HHA identify if the patient is in need of mental or behavioral health supervision. This requirement is based on the SOC/ROC code for M2102f, Types and Sources of Assistance: Supervision and Safety. If the HHA codes a value of 0, then the HHA has identified this patient as not needing mental or behavioral health supervision. If the HHA codes another value for M2102f, Types and Sources of Assistance: Supervision and Safety, then the HHA has identified this patient as needing mental or behavioral health supervision. The outcome measure is defined as the agreement between the algorithm's identification of a patient's need for mental or behavioral health supervision and the HHA's coding of this need. That is, if—

- The algorithm identifies the patient as not in need of mental or behavioral health supervision and the HHA identifies the patient as not in need of mental or behavioral health supervision, or
- The algorithm identifies the patient as in need of mental or behavioral health supervision and the HHA identifies the patient as in need of mental or behavioral health supervision, then
- The outcome is coded as 1, successful.

As with other OASIS-based measures, a performance score for the measure would only be calculated for HHAs that have 20 or more episodes of care during a performance year.

The measure is risk-adjusted using OASIS–C2 items to account for case-mix variation and other factors that affect functional decline but are beyond the influence of the HHA. The risk-adjustment model uses a logistic regression framework. The model includes a large number of patient clinical conditions and other characteristics measured at the start of care. To calculate case-mix adjusted values, the observed value of the measure is adjusted by the difference between the HHA predicted percent and the national predicted percent.

The prediction model for this outcome measure uses 39 risk factors¹⁰⁶ with each risk factor statistically significant at <0.0001. The correlation for the model between observed and predicted values as estimated by

¹⁰⁶ “Home Health Quality Initiative: Quality Measures” <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html>.

Somers' D¹⁰⁷ is 0.427, that yields an estimated coefficient of determination (r^2) value based on the Tau-a¹⁰⁸ of 0.201. This suggests that the variability in the model accounts for (predicts) approximately 20 percent of the variability in the outcome measure. The best statistic for evaluating the power of a prediction model that is derived using logistic regression is the c-statistic.¹⁰⁹ This statistic identifies the overall accuracy of prediction by comparing observed and predicted value pairs to the proportion of the time that both predict the outcome in the same direction with 0.500 being a coin-flip. The discussed prediction model has a c-statistic equal to 0.713, which is considered to be strong. Using data from CY 2015, the episode-level mean for the HHA Correctly Identifies Patient's Need for Mental or Behavioral Health Supervision measure is 61.98 percent, nationally, and 62.98 percent for the HHVBP states.

b. Caregiver Can/Does Provide for Patient's Mental or Behavioral Health Supervision Need

We are considering including under the Model in future rulemaking a *Caregiver Can/Does Provide for Patient's Mental or Behavioral Health Supervision Need* measure that would encourage HHAs to ensure that patients who need mental or behavioral health supervision are receiving such care from the patient's caregivers, and would be a realistic care goal.

¹⁰⁷ Somers' D is a statistic that is based on the concept of concordant vs. discordant pairs for two related values. In this case, if both the observed and predicted values are higher than the average or if both values are less than the average, then the pair of numbers is considered concordant. However, if one value is higher than average and the other is lower than average—or vice versa, then the pair of values is considered discordant. The Somers' D is (# of concordant pairs – # of discordant pairs)/total # of pairs. The higher the ratio, the stronger the concordance between the two set of values.

¹⁰⁸ The Kendall Tau-a assumes that if there is a correlation between two variables, then sorting the variables based on one of the values will result in ordering the second variable. It uses the same concept of concordant pairs in Somers' D but a different formula: $t = [(4P)/((n)(n-1))] - 1$ where p = # of concordant pairs and n = # of pairs. This correlation method reduces the effect of outlier values as the values are essentially ranked.

¹⁰⁹ The C-statistic (sometimes called the "concordance" statistic or C-index) is a measure of goodness of fit for binary outcomes in a logistic regression model. In clinical studies, the C-statistic gives the probability a randomly selected patient who experienced an event (for example, a disease or condition) had a higher risk score than a patient who had not experienced the event. It is equal to the area under the Receiver Operating Characteristic (ROC) curve and ranges from 0.5 to 1.

- A value below 0.5 indicates a very poor model.
- A value of 0.5 means that the model is no better than predicting an outcome than random chance.
- Values over 0.7 indicate a good model.
- Values over 0.8 indicate a strong model.

When considering how to develop a measure to determine whether or not the caregiver can/does provide the patient's mental or behavioral health supervision, we would create an identifier of a patient's need for mental or behavioral health supervision. This identifier is based on the same algorithm described in the previous section from existing Neuro/Emotional/Behavioral Status OASIS items along with other indicators of mental/behavioral health problems to identify a patient in need of supervisory assistance. The outcome measure is whether the HHA correctly identifies this patient as having the need for mental or behavioral health supervision based on the OASIS SOC/ROC assessment item M2102f, Types and Sources of Assistance: Supervision and Safety.

The measure could be a dichotomous measure that reports the percentage of episodes where patients with identified mental or behavioral health supervision needs have their needs met or could have their needs met by the patient's caregiver with additional training (if needed) and support by the HHA. The numerator is the intersection of: (1) The number of episodes of care where the patient needs mental or behavioral health supervision; and (2) the number of episodes of care where these patients have their needs met or could have their needs met by the patient's caregiver with additional training (if needed) and support by the HHA. By intersection, we mean that, for the numerator to equal one, a patient has to need mental or behavioral health supervision and has to have these needs met by his or her caregiver, or could have their needs met by the caregiver with additional training and/or support by the HHA. The denominator is all episodes of care. The algorithm discussed above for *HHA Correctly Identifies Patient's Need for Mental or Behavioral Health Supervision* could also be used to first identify if a patient was in need of mental or behavioral health supervision.

To identify whether caregivers are able to provide supervisory care or, with training, could be able to provide supervisory care for these patients, we could use the SOC/ROC code for M2102f, Types and Sources of Assistance: Supervision and Safety. If the HHA codes a value of 1 (Non-agency caregiver(s) currently provide assistance) or 2 (Non-agency caregiver(s) need training/supportive services to provide assistance), then the measure identifies that a caregiver does or could provide supervision to a patient who has been identified as needing mental or behavioral health supervision.

The outcome measure is defined as the agreement between the algorithm's identification of a patient's need for mental or behavioral health supervision and the availability of supervision from the patient's caregiver(s). That is, if—

- The algorithm identifies the patient as in need of mental or behavioral health supervision and there is documentation that the patient's caregiver(s) do or could provide this supervision; then
- The outcome is coded as 1, successful.

As with other OASIS-based measures, a performance score for the measure would only be calculated for HHAs that have 20 or more episodes during a performance year. We would use the same methodology to risk-adjust by using OASIS-C2 items and the prediction model described above. The prediction model for this outcome measure uses 55 risk factors with each risk factor significant at $p < 0.0001$. The correlation for the model between observed and predicted values as estimated by Somers' D is 0.672, that yields an estimated coefficient of determination (r^2) value based on the Tau-a of 0.205. This suggests that the variability in the model accounts for (predicts) approximately 20 percent of the variability in the outcome measure. The best statistic for evaluating the power of a prediction model that is derived using logistic regression is the c-statistic. This statistic identifies the overall accuracy of prediction by comparing observed and predicted value pairs to the proportion of the time that both predict the outcome in the same direction with 0.500 being a coin-flip. The prediction model has a c-statistic equal to 0.836, which is considered to be extremely strong.

We are considering whether the *HHA Correctly Identifies Patient's Need for Mental or Behavioral Health Supervision* measure or the *Caregiver Can/Does Provide for Patient's Mental or Behavioral Health Supervision Need* measure would be most meaningful to include in the Model. We are also considering the interactions between the Home Health Grouping Model (HHGM) proposal on quality measures discussed in section III of this proposed rule and the HHVBP Model for the quality measures discussed in section IV.B of this proposed rule. We are soliciting public comments on the methodologies, analyses used to test the quality measure, and issues described in this section for future measure considerations. We will continue to share analyses as they become available with participating HHAs during future webinars.

V. Proposed Updates to the Home Health Care Quality Reporting Program (HH QRP)

A. Background and Statutory Authority

Section 1895(b)(3)(B)(v)(II) of the Act requires that for 2007 and subsequent years, each HHA submit to the Secretary in a form and manner, and at a time, specified by the Secretary, such data that the Secretary determines are appropriate for the measurement of health care quality. To the extent that an HHA does not submit data in accordance with this clause, the Secretary is directed to reduce the home health market basket percentage increase applicable to the HHA for such year by 2 percentage points. As provided at section 1895(b)(3)(B)(vi) of the Act, depending on the market basket percentage increase applicable for a particular year, the reduction of that increase by 2 percentage points for failure to comply with the requirements of the HH QRP, and further reduction of the increase by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, may result in the home health market basket percentage increase being less than 0.0 percent for a year, and may result in payment rates under the Home Health PPS for a year being less than payment rates for the preceding year.

We use the terminology “CY [year] HH QRP” to refer to the calendar year for which the HH QRP requirements applicable to that calendar year must be met in order for an HHA to avoid a 2 percentage point reduction to its market basket percentage increase under section 1895(b)(3)(B)(v)(I) of the Act when calculating the payment rates applicable to it for that calendar year.

The Improving Medicare Post-Acute Care Transformation Act of 2014 (Pub. L. 113–185, enacted on October 6, 2014) (IMPACT Act) amended Title XVIII of the Act, in part, by adding new section 1899B of the Act, entitled “Standardized Post-Acute Care Assessment Data for Quality, Payment, and Discharge Planning,” and by enacting new data reporting requirements for certain post-acute care (PAC) providers, including Home Health Agencies (HHAs). Specifically, new sections 1899B(a)(1)(A)(ii) and (iii) of the Act require HHAs, Inpatient Rehabilitation Facilities (IRFs), Long Term Care Hospitals (LTCHs) and Skilled Nursing Facilities (SNFs), under each of their respective quality reporting program (which, for HHAs, is found at section 1895(b)(3)(B)(v) of the Act), to report data on quality measures specified under section 1899B(c)(1) of the Act for at least five domains, and

data on resource use and other measures specified under section 1899B(d)(1) of the Act for at least three domains. Section 1899B(a)(1)(A)(i) of the Act further requires each of these PAC providers to report under their respective quality reporting program standardized patient assessment data in accordance with subsection (b) for at least the quality measures specified under subsection (c)(1) and that is for five specific categories: Functional status; cognitive function and mental status; special services, treatments, and interventions; medical conditions and co-morbidities; and impairments. All of the data that must be reported in accordance with section 1899B(a)(1)(A) of the Act must be standardized and interoperable, so as to allow for the exchange of the information among PAC providers and other providers, as well as for the use of such data to enable access to longitudinal information and to facilitate coordinated care. We refer readers to the CY 2016 HH PPS final rule (80 FR 68690 through 68692) for additional information on the IMPACT Act and its applicability to HHAs.

B. General Considerations Used for the Selection of Quality Measures for the HH QRP

We refer readers to the CY 2016 HH PPS final rule (80 FR 68695 through 68698) for a detailed discussion of the considerations we apply in measure selection for the HH QRP, such as alignment with the CMS Quality Strategy,¹¹⁰ which incorporates the three broad aims of the National Quality Strategy.¹¹¹ As part of our consideration for measures for use in the HH QRP, we review and evaluate measures that have been implemented in other programs and take into account measures that have been endorsed by NQF for provider settings other than the HH setting. We have previously adopted measures with the term “Application of” in the names of those measures. We have received questions pertaining to the term “application” and want to clarify that when we refer to a measure as an “Application of” the measure, we mean that the measure would be used in a setting other than the setting for which it was endorsed by the NQF. For example, in the FY 2016 SNF PPS Rule (80 FR 46440 through 46444 we adopted an Application of Percent of Residents with Experiencing Falls with Major Injury (Long Stay) (NQF #0674), which

is endorsed for the Nursing Home setting but not the SNF setting. For such measures, we intend to seek NQF endorsement for the HH setting, and if the NQF endorses one or more of them, we will update the title of the measure to remove the reference to “Application of.”

C. Accounting for Social Risk Factors in the HH QRP

We consider related factors that may affect measures in the HH QRP. We understand that social risk factors such as income, education, race and ethnicity, employment, disability, community resources, and social support (certain factors of which are also sometimes referred to as socioeconomic status (SES) factors or socio-demographic status (SDS) factors) play a major role in health. One of our core objectives is to improve beneficiary outcomes including reducing health disparities, and we want to ensure that all beneficiaries, including those with social risk factors, receive high quality care. In addition, we seek to ensure that the quality of care furnished by providers and suppliers is assessed as fairly as possible under our programs while ensuring that beneficiaries have adequate access to excellent care.

We have been reviewing reports prepared by the Office of the Assistant Secretary for Planning and Evaluation (ASPE¹¹²) and the National Academies of Sciences, Engineering, and Medicine on the issue of measuring and accounting for social risk factors in CMS’ value-based purchasing and quality reporting programs, and considering options on how to address the issue in these programs. On December 21, 2016, ASPE submitted a Report to Congress on a study it was required to conduct under section 2(d) of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. The study analyzed the effects of certain social risk factors of Medicare beneficiaries on quality measures and measures of resource use used in one or more of nine Medicare value-based purchasing programs.¹¹³ The report also included considerations for strategies to account for social risk factors in these programs. In a January 10, 2017 report released by The National Academies of Sciences, Engineering, and Medicine, that body provided various potential

¹¹² <https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicare-value-based-purchasing-programs>.

¹¹³ <https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicare-value-based-purchasing-programs>.

¹¹⁰ <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Quality-InitiativesGenInfo/CMS-Quality-Strategy.html>.

¹¹¹ <http://www.ahrq.gov/workingforquality/nqs/nqs2011annlrpt.htm>.

methods for measuring and accounting for social risk factors, including stratified public reporting.¹¹⁴

As discussed in the CY 2017 HH PPS final rule, the NQF has undertaken a 2-year trial period in which new measures, measures undergoing maintenance review, and measures endorsed with the condition that they enter the trial period can be assessed to determine whether risk adjustment for selected social risk factors is appropriate for these measures. Measures from the HH QRP, Rehospitalization During the First 30 Days of Home Health (NQF #2380), and Emergency Department Use without Hospital Readmission During the First 30 Days of Home Health (NQF #2505) are being addressed in this trial. This trial entails temporarily allowing inclusion of social risk factors in the risk-adjustment approach for these measures. At the conclusion of the trial, NQF will issue recommendations on the future inclusion of social risk factors in risk adjustment for quality measures.

As we continue to consider the analyses and recommendations from these reports and await the results of the NQF trial on risk adjustment for quality measures, we are continuing to work with stakeholders in this process. As we have previously communicated, we are concerned about holding providers to different standards for the outcomes of their patients with social risk factors because we do not want to mask potential disparities or minimize incentives to improve the outcomes for

disadvantaged populations. Keeping this concern in mind, while we sought input on this topic previously, we continue to seek public comment on whether we should account for social risk factors in measures in the HH QRP, and if so, what method or combination of methods would be most appropriate for accounting for social risk factors. Examples of methods include: Confidential reporting to providers of measure rates stratified by social risk factors, public reporting of stratified measure rates, and potential risk adjustment of a particular measure as appropriate based on data and evidence.

In addition, we are seeking public comment on which social risk factors might be most appropriate for reporting stratified measure scores and potential risk adjustment of a particular measure. Examples of social risk factors include, but are not limited to, dual eligibility/low-income subsidy, race and ethnicity, and geographic area of residence. We are seeking comments on which of these factors, including current data sources where this information would be available, could be used alone or in combination, and whether other data should be collected to better capture the effects of social risk. We will take commenters' input into consideration as we continue to assess the appropriateness and feasibility of accounting for social risk factors in the HH QRP. We note that any such changes would be proposed through future notice and comment rulemaking.

We look forward to working with stakeholders as we consider the issue of accounting for social risk factors and reducing health disparities in CMS programs. Of note, implementing any of the above methods would be taken into consideration in the context of how this and other CMS programs operate (for example, data submission methods, availability of data, statistical considerations relating to reliability of data calculations, among others), so we also welcome comment on operational considerations. We are committed to ensuring that beneficiaries have access to and receive excellent care, and that the quality of care furnished by providers and suppliers is assessed fairly in CMS programs.

D. Proposed Data Elements for Removal From OASIS

We are proposing to remove 247 data elements from 35 OASIS items collected at specific time points during a home health episode. These data elements are not used in the calculation of quality measures already adopted in the HH QRP, nor are they being used for previously established purposes unrelated to the HH QRP, including payment, survey, the HH VBP Model or care planning. A list of the proposed 35 OASIS items and data elements are listed in Table 45 and also at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/OASIS-Data-Sets.html>.

TABLE 45—PROPOSED DATA ELEMENTS TO BE REMOVED FROM OASIS ON JANUARY 1, 2019

OASIS item	Specific time point					
	Start of care	Resumption of care	Follow-up	Transfer to an inpatient facility	Death at home	Discharge from agency
M0903				1	1	1
M1011	6	6	6			
M1017	6	6				
M1018	6	6				
M1025	12	12	12			
M1034	1	1				
M1036	4	4				
M1200	1	1	1			
M1210	1	1				
M1220	1	1				
M1230	1	1				1
M1240	1	1				
M1300	1	1				
M1302	1	1				
M1320	1	1				1
M1322						1
M1332						1
M1350	1	1				
M1410	3	3				
M1501				1		1

¹¹⁴ National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk

factors in Medicare payment. Washington, DC: The National Academies Press.

TABLE 45—PROPOSED DATA ELEMENTS TO BE REMOVED FROM OASIS ON JANUARY 1, 2019—Continued

OASIS item	Specific time point					
	Start of care	Resumption of care	Follow-up	Transfer to an inpatient facility	Death at home	Discharge from agency
M1511				5		5
M1610						1
M1615	1	1				1
M1730	3	3				
M1750	1	1				
M1880	1	1				1
M1890	1	1				1
M1900	4	4				
M2030	1	1	1			1
M2040	2	2				
M2102 *	6	6				** 3
M2110	1	1				
M2250	7	7				
M2310				*** 15		*** 15
M2430				20		
Total	75	75	20	42	1	34

* M2102 row f to remain collected at Start of Care, Resumption of Care and Discharge from Agency as part of the HH VBP program.

** M2102 rows a,c,d to remain collected at Discharge from Agency for survey purposes.

*** M2310 responses 1,10,OTH,UK to remain collected at Transfer to an Inpatient Facility and Discharge from Agency for survey purposes.

We are inviting public comment on this proposal.

E. Proposed Collection of Standardized Patient Assessment Data Under the HH QRP

1. Proposed Definition of Standardized Patient Assessment Data

Section 1895(b)(3)(B)(v)(IV)(bb) of the Act requires that beginning with the CY 2019 HH QRP, HHAs report standardized patient assessment data required under section 1899B(b)(1) of the Act. For purposes of meeting this requirement, section 1895(b)(3)(B)(v)(IV)(cc) of the Act requires that a HHA submit the standardized patient assessment data required under section 1899B(b)(1) of the Act in the form and manner, and at the time, as specified by the Secretary.

Section 1899B(b)(1)(B) of the Act describes standardized patient assessment data as data required for at least the quality measures described in sections 1899B(c)(1) of the Act and regarding the following categories:

- Functional status, such as mobility and self-care at admission to a PAC provider and before discharge from a PAC provider;
- Cognitive function, such as ability to express and understand ideas, and mental status, such as depression and dementia;
- Special services, treatments and interventions such as the need for ventilator use, dialysis, chemotherapy, central line placement, and total parenteral nutrition;

- Medical conditions and comorbidities such as diabetes, congestive heart failure and pressure ulcers;

- Impairments, such as incontinence and an impaired ability to hear, see or swallow; and

- Other categories deemed necessary and appropriate by the Secretary.

As required under section 1899B(b)(1)(A) of the Act, the standardized patient assessment data must be reported at least for the beginning of the home health episode (for example, HH start of care/resumption of care) and end of episode (discharge), but the Secretary may require the data to be reported more frequently.

In this proposed rule, we are proposing to define the standardized patient assessment data that HHAs must report under the HH QRP, as well as the requirements for the reporting of these data. The collection of standardized patient assessment data is critical to our efforts to drive improvement in healthcare quality across the four post-acute care (PAC) settings to which the IMPACT Act applies. We intend to use these data for a number of purposes, including facilitating their exchange and longitudinal use among healthcare providers to enable high quality care and outcomes through care coordination, as well as for quality measure calculation, and identifying comorbidities that might increase the medical complexity of a particular admission.

HHAs are currently required to report patient assessment data through the Outcome and Assessment Information Set (OASIS) by responding to an identical set of assessment questions using an identical set of response options (we refer to a solitary question/response option as a data element and we refer to a group of questions/responses as data elements), both of which incorporate an identical set of definitions and standards. The primary purpose of the identical questions and response options is to ensure that we collect a set of standardized data elements across HHAs, which we can then use for a number purposes, including HH payment and measure calculation for the HH QRP.

LTCHs, IRFs, and SNFs are also required to report patient assessment data through their applicable PAC assessment instruments, and they do so by responding to identical assessment questions developed for their respective settings using an identical set of response options (which incorporate an identical set of definitions and standards). Like the OASIS, the questions and response options for each of these other PAC assessment instruments are standardized across the PAC provider type to which the PAC assessment instrument applies. However, the assessment questions and response options in the four PAC assessment instruments are not currently standardized with each other. As a result, questions and response options that appear on the OASIS

cannot be readily compared with questions and response options that appear, for example, on the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF-PAI) the PAC assessment instrument used by IRFs. This is true even when the questions and response options are similar. This lack of standardization across the four PAC provider types has limited our ability to compare one PAC provider type with another for purposes such as care coordination and quality improvement.

To achieve a level of standardization across HHAs, LTCHs, IRFs, and SNFs that enables us to make comparisons between them, we are proposing to define “standardized patient assessment data” as patient or resident assessment questions and response options that are identical in all four PAC assessment instruments, and to which identical standards and definitions apply. Standardizing the questions and response options across the four PAC assessment instruments is an essential step in making that data interoperable, allowing it to be shared electronically, or otherwise, between PAC provider types. It will enable the data to be comparable for various purposes, including the development of cross-setting quality measures and to inform payment models that take into account patient characteristics rather than setting, as described in the IMPACT Act.

We are inviting public comment on this proposed definition.

2. General Considerations Used for the Selection of Proposed Standardized Patient Assessment Data

As part of our effort to identify appropriate standardized patient assessment data for purposes of collecting under the HH QRP, we sought input from the general public, stakeholder community, and subject matter experts on items that would enable person-centered, high quality health care, as well as access to longitudinal information to facilitate coordinated care and improved beneficiary outcomes.

To identify optimal data elements for standardization, our data element contractor organized teams of researchers for each category, with each team working with a group of advisors made up of clinicians and academic researchers with expertise in PAC. Information-gathering activities were used to identify data elements, as well as key themes related to the categories described in section 1899B(b)(1)(B) of the Act. In January and February 2016, our data element contractor also conducted provider focus groups for

each of the four PAC provider types, and a focus group for consumers that included current or former PAC patients and residents, caregivers, ombudsmen, and patient advocacy group representatives. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data Focus Group Summary Report is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Our data element contractor also assembled a 16-member TEP that met on April 7 and 8, 2016, and January 5 and 6, 2017, in Baltimore, Maryland, to provide expert input on data elements that are currently in each PAC assessment instrument, as well as data elements that could be standardized. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data TEP Summary Reports are available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

As part of the environmental scan, data elements currently in the four existing PAC assessment instruments were examined to see if any could be considered for proposal as standardized patient assessment data. Specifically, this evaluation included consideration of data elements in OASIS-C2 (effective January 2017); IRF-PAI, v1.4 (effective October 2016); LCDS, v3.00 (effective April 2016); and MDS 3.0, v1.14 (effective October 2016). Data elements in the standardized assessment instrument that we tested in the Post-Acute Care Payment Reform Demonstration (PAC PRD)—the Continuity Assessment Record and public reporting Evaluation (CARE)—were also considered. A literature search was also conducted to determine whether additional data elements to propose as standardized patient assessment data could be identified.

Additionally, we held four Special Open Door Forums (SODFs) on October 27, 2015; May 12, 2016; September 15, 2016; and December 8, 2016, to present data elements we were considering and to solicit input. At each SODF, some stakeholders provided immediate input, and all were invited to submit additional comments via the CMS IMPACT Mailbox: PACQualityInitiative@cms.hhs.gov.

We also convened a meeting with federal agency subject matter experts (SMEs) on May 13, 2016. In addition, a public comment period was open from August 12 to September 12, 2016 to solicit comments on detailed candidate data element descriptions, data collection methods, and coding methods. The IMPACT Act Public Comment Summary Report containing the public comments (summarized and verbatim) and our responses is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We specifically sought to identify standardized patient assessment data that we could feasibly incorporate into the LTCH, IRF, SNF, and HHA assessment instruments and that have the following attributes: (1) Being supported by current science; (2) testing well in terms of their reliability and validity, consistent with findings from the Post-Acute Care Payment Reform Demonstration (PAC PRD); (3) the potential to be shared (for example, through interoperable means) among PAC and other provider types to facilitate efficient care coordination and improved beneficiary outcomes; (4) the potential to inform the development of quality, resource use and other measures, as well as future payment methodologies that could more directly take into account individual beneficiary health characteristics; and (5) the ability to be used by practitioners to inform their clinical decision and care planning activities. We also applied the same considerations that we apply with quality measures, including the CMS Quality Strategy which is framed using the three broad aims of the National Quality Strategy.

3. Policy for Retaining HH QRP Measures and Proposal To Apply That Policy to Standardized Patient Assessment Data

In the CY 2017 HH PPS final rule (81 FR 76702), we adopted a policy that would allow for any quality measure adopted for use in the HH QRP to remain in effect until the measure is removed, suspended, or replaced. For further information on how measures are considered for removal, suspension or replacement, we refer readers to the CY 2017 HH PPS final rule (81 FR 76702). We propose to apply this same policy to the standardized patient assessment data that we adopt for the HH QRP.

We are inviting public comment on our proposal.

4. Policy for Adopting Changes to HH QRP Measures and Proposal To Apply That Policy to Standardized Patient Assessment Data

In the CY 2017 HH PPS final rule (81 FR 76702), we adopted a subregulatory process to incorporate updates to HH quality measure specifications that do not substantively change the nature of

the measure. Substantive changes will be proposed and finalized through rulemaking. For further information on what constitutes a substantive versus a nonsubstantive change and the subregulatory process for nonsubstantive changes, we refer readers to the CY 2017 HH PPS final rule (81 FR 76702). We propose to apply this policy to the standardized patient

assessment data that we adopt for HH QRP.

We are inviting public comment on our proposal.

5. Quality Measures Previously Finalized for the HH QRP

The HH QRP currently has 23 measures, as outlined in Table 47.

TABLE 47—MEASURES CURRENTLY ADOPTED FOR THE HH QRP

Short name	Measure name & data source
OASIS-based	
Pressure Ulcers	Percent of Patients or Residents with Pressure Ulcers that are New or Worsened (NQF #0678).*+
DRR	Drug Regimen Review Conducted with Follow-Up for Identified Issues-Post Acute Care (PAC) Home Health Quality Reporting Program.+
Ambulation	Improvement in Ambulation/Locomotion (NQF #0167).
Bathing	Improvement in Bathing (NQF #0174).
Dyspnea	Improvement in Dyspnea.
Oral Medications	Improvement in Management of Oral Medication (NQF #0176).
Pain	Improvement in Pain Interfering with Activity (NQF #0177).
Surgical Wounds	Improvement in Status of Surgical Wounds (NQF #0178).
Bed Transferring	Improvement in Bed Transferring (NQF #0175).
Timely Care	Timely Initiation Of Care (NQF #0526).
Depression Assessment	Depression Assessment Conducted.
Influenza	Influenza Immunization Received for Current Flu Season (NQF #0522).
PPV	Pneumococcal Polysaccharide Vaccine Ever Received (NQF #0525).
Falls Risk	Multifactor Fall Risk Assessment Conducted For All Patients Who Can Ambulate (NQF #0537).
Diabetic Foot Care	Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care (NQF #0519).
Drug Education	Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care.
Claims-based	
MSPB	Total Estimated Medicare Spending Per Beneficiary (MSPB)—Post Acute Care (PAC) Home Health (HH) Quality Reporting Program (QRP).+
DTC	Discharge to Community-Post Acute Care (PAC) Home Health (HH) Quality Reporting Program (QRP).+
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for Home Health Quality Reporting Program.+
ACH	Acute Care Hospitalization During the First 60 Days of Home Health (NQF #0171).
ED Use	Emergency Department Use without Hospitalization During the First 60 Days of Home Health (NQF #0173).
Rehospitalization	Rehospitalization During the First 30 Days of Home Health (NQF #2380).
ED Use without Readmission	Emergency Department Use without Hospital Readmission During the First 30 Days of Home Health (NQF #2505).
HHCAHPs-based	
Professional Care	How often the home health team gave care in a professional way.
Communication	How well did the home health team communicate with patients.
Team Discussion	Did the home health team discuss medicines, pain, and home safety with patients.
Overall Rating	How do patients rate the overall care from the home health agency.
Willing to Recommend	Would patients recommend the home health agency to friends and family.

* Not currently NQF-endorsed for the HH Setting.

+ The data collection period will begin with CY 2017 Q1&2 reporting for CY 2018 APU determination, followed by the previously established HH QRP use of 12 months (July 1, 2017–June 30, 2018) of CY 2017 reporting for CY 2019 APU determination. Subsequent years will be based on the HH July 1–June 30 timeframe for APU purposes. For claims data, the performance period will use rolling CY claims for subsequent reporting purposes.

F. HH QRP Quality Measures Proposed Beginning With the CY 2020 HH QRP

Beginning with the CY 2020 HH QRP, in addition to the quality measures we are retaining under our policy described in section V.B. of the preamble of this proposed rule, we are proposing to replace the current pressure ulcer measure entitled Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF

#0678) with a modified version of the measure and to adopt one measure on patient falls and one measure on assessment of patient functional status. We are also proposing to characterize the data elements described below, as standardized patient assessment data under section 1899B(b)(1)(B) of the Act that must be reported by HHAs under the HH QRP through the OASIS, under

section 1895(b)(3)(B)(v) of the Act. The proposed measures are as follows:

- Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury.
- Application of Percent of Residents Experiencing One or More Falls with Major Injury (NQF #0674).
- Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional

Assessment and a Care Plan That Addresses Function (NQF #2631).

The measures are described in more detail below.

1. Proposal To Replace the Current Pressure Ulcer Quality Measure, Entitled Percent of Residents or Patients With Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), With a Modified Pressure Ulcer Measure, Entitled Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury

a. Measure Background

In this rule, we are proposing to remove the current pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), from the HH QRP measure set and to replace it with a modified version of that measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, beginning with the CY 2020 HH QRP. The change in the measure name is to reduce confusion about the new modified measure. The modified version differs from the current version of the measure because it includes new or worsened unstageable pressure ulcers, including deep tissue injuries (DTIs), in the measure numerator. The proposed modified version of the measure also contains updated specifications intended to eliminate redundancies in the assessment items needed for its calculation and to reduce the potential for underestimating the frequency of pressure ulcers. The modified version of the measure would satisfy the IMPACT Act domain of "Skin integrity and changes in skin integrity."

b. Measure Importance

As described in the CY 2016 HH PPS final rule (80 FR 68697), pressure ulcers are high-cost adverse events and are an important measure of quality. For information on the history and rationale for the relevance, importance, and applicability of having a pressure ulcer measure in the HH QRP, we refer readers to the CY 2016 HH PPS final rule (80 FR 68623).

We are proposing to adopt a modified version of the current pressure ulcer measure because unstageable pressure ulcers, including DTIs, are similar to Stage 2, Stage 3, and Stage 4 pressure ulcers in that they represent poor outcomes, are a serious medical condition that can result in death and disability, are debilitating and painful and are often an avoidable outcome of

medical care.^{115 116 117 118 119 120} Studies show that most pressure ulcers can be avoided and can also be healed in acute, post-acute, and long term care settings with appropriate medical care.¹²¹ Furthermore, some studies indicate that DTIs, if managed using appropriate care, can be resolved without deteriorating into a worsened pressure ulcer.^{122 123}

While there are few studies that provide information regarding the incidence of unstageable pressure ulcers in PAC settings, an analysis conducted by our measure development contractor indicated that adding unstageable pressure ulcers to the quality measure numerator would result in a higher percentage of patients with new or worsened pressure ulcers in HHA settings and increase the variability of measure scores. A higher percentage indicates lower quality. This increased variability serves to improve the measure by improving the ability of the measure to distinguish between high and low quality home health agencies.

Given the low prevalence of pressure ulcers in the home health setting, the addition of unstageable ulcers to this measure should enhance variability. Analysis of 2015 OASIS data found that in approximately 1.2 percent, or more than 70,000 episodes, the patient had an unstageable ulcer upon admission. Patients in more than 13,000 episodes were discharged with an unstageable ulcer. In addition, unstageable ulcers

¹¹⁵ Casey, G. (2013). "Pressure ulcers reflect quality of nursing care." *Nurs N Z* 19(10): 20–24.

¹¹⁶ Gorzoni, M.L. and S.L. Pires (2011). "Deaths in nursing homes." *Rev Assoc Med Bras* 57(3): 327–331.

¹¹⁷ Thomas, J.M., et al. (2013). "Systematic review: health-related characteristics of elderly hospitalized adults and nursing home residents associated with short-term mortality." *J Am Geriatr Soc* 61(6): 902–911.

¹¹⁸ White-Chu, E.F., et al. (2011). "Pressure ulcers in long-term care." *Clin Geriatr Med* 27(2): 241–258.

¹¹⁹ Bates-Jensen BM. Quality indicators for prevention and management of pressure ulcers in vulnerable elders. *Ann Int Med*. 2001;135 (8 Part 2), 744–51.

¹²⁰ Bennet, G, Dealy, C, Posnett, J (2004). The cost of pressure ulcers in the UK, *Age and Aging*, 33(3):230–235.

¹²¹ Black, Joyce M., et al. "Pressure ulcers: avoidable or unavoidable? Results of the national pressure ulcer advisory panel consensus conference." *Ostomy-Wound Management* 57.2 (2011): 24.

¹²² Sullivan, R. (2013). A Two-year Retrospective Review of Suspected Deep Tissue Injury Evolution in Adult Acute Care Patients. *Ostomy Wound Management* 59(9) <http://www.o-wm.com/article/two-year-retrospective-review-suspected-deep-tissue-injury-evolution-adult-acute-care-patient>.

¹²³ Posthauer, ME, Zulkowski, K. (2005). Special to OWM: The NPUAP Dual Mission Conference: Reaching Consensus on Staging and Deep Tissue Injury. *Ostomy Wound Management* 51(4) <http://www.o-wm.com/content/the-npuap-dual-mission-conference-reaching-consensus-staging-and-deep-tissue-injury>.

due to slough/eschar worsened between admission and discharge in approximately 5,000 episodes of care. In conclusion, the inclusion of unstageable pressure ulcers, including DTIs, in the numerator of this measure is expected to increase measure scores and variability in measure scores, thereby improving the ability to discriminate among poor- and high-performing HHAs.

Testing shows similar results in other PAC settings. For example, in SNFs, using data from Quarter 4 2015 through Quarter 3 2016, the mean score on the currently implemented pressure ulcer measure is 1.75 percent, compared with 2.58 percent in the proposed measure. In the proposed measure, the SNF mean score is 2.58 percent; the 25th and 75th percentiles are 0.65 percent and 3.70 percent, respectively; and 20.32 percent of facilities have perfect scores. In LTCHs, using data from Quarter 1 through Quarter 4 2015, the mean score on the currently implemented pressure ulcer measure is 1.95 percent, compared with 3.73 percent in the proposed measure. In the proposed measure, the LTCH mean score is 3.73 percent; the 25th and 75th percentiles are 1.53 percent and 4.89 percent, respectively; and 5.46 percent of facilities have perfect scores. In IRFs, using data from Quarter 4 2016, the mean score on the currently implemented pressure ulcer measure is 0.64 percent, compared with 1.46 percent in the proposed measure. In the proposed measure, the IRF mean score is 1.46 percent and the 25th and 75th percentiles are 0 percent and 2.27 percent, respectively. The inclusion of unstageable pressure ulcers, including DTIs, in the numerator of this measure is expected to increase measure scores and variability in measure scores, thereby improving the ability to distinguish between poor and high performing HHAs.

This increased variability of scores across quarters and deciles may improve the ability of the measure to distinguish between high and low performing providers across PAC settings.

c. Stakeholder Feedback

Our measure development contractor sought input from subject matter experts, including Technical Expert Panels (TEPs), over the course of several years on various skin integrity topics and specifically those associated with the inclusion of unstageable pressure ulcers including DTIs. Most recently, on July 18, 2016, a TEP convened by our measure development contractor provided input on the technical specifications of this proposed quality measure, including the feasibility of implementing the proposed measure's

updates across PAC settings. The TEP supported the use of the proposed measure across PAC settings, including the use of different data elements for measure calculation. The TEP supported the updates to the measure across PAC settings, including the inclusion in the numerator of unstageable pressure ulcers due to slough and/or eschar that are new or worsened, new unstageable pressure ulcers due to a non-removable dressing or device, and new DTIs. The TEP recommended supplying additional guidance to providers regarding each type of unstageable pressure ulcer. This support was in agreement with earlier TEP meetings, held on June 13, and November 15, 2013, which had recommended that CMS update the specifications for the pressure ulcer measure to include unstageable pressure ulcers in the numerator.^{124 125} Exploratory data analysis conducted by our measure development contractor suggests that the addition of unstageable pressure ulcers, including DTIs, will increase the observed incidence of new or worsened pressure ulcers at the facility level and may improve the ability of the proposed quality measure to discriminate between poor- and high-performing agencies.

We solicited stakeholder feedback on this proposed measure by means of a public comment period held from October 17, through November 17, 2016. In general, we received considerable support for the proposed measure. A few commenters supported all of the changes to the current pressure ulcer measure that resulted in the proposed measure, with one commenter noting the significance of the work to align the pressure ulcer quality measure specifications across the PAC settings. Many commenters supported the inclusion of unstageable pressure ulcers due to slough/eschar, due to non-removable dressing/device, and DTIs in

the proposed quality measure. Other commenters did not support the inclusion of DTIs in the proposed quality measure because they stated that there is no universally accepted definition for this type of skin injury.

Some commenters provided feedback on the data elements used to calculate the proposed quality measure. We believe that these data elements will promote facilitation of cross-setting quality comparison as mandated by the IMPACT Act, alignment between quality measures and payment, reduction in redundancies in assessment items, and prevention of inappropriate underestimation of pressure ulcers. The currently implemented pressure ulcer measure is calculated using retrospective data elements that assess the number of new or worsened pressure ulcers at each stage, while the proposed measure is calculated using data elements that assess the current number of unhealed pressure ulcers at each stage, and the number of these that were present upon admission, which are subtracted from the current number at that stage. Some commenters did not support the data elements that would be used to calculate the proposed measure, and requested further testing of these data elements. Other commenters supported the use of these data elements stating that these data elements simplified the measure calculation process.

The public comment summary report for the proposed measure is available on the CMS Web site at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

The NQF-convened Measures Application Partnership (MAP) Post-Acute Care/Long-Term Care (PAC/LTC) Workgroup met on December 14 and 15, 2016, and provided input to us about this proposed measure. The MAP provided a recommendation of “support for rulemaking” for use of the proposed measure in the HH QRP. The MAP Coordinating Committee met on January 24 and 25, 2017, and provided a recommendation of “conditional support for rulemaking” for use of the proposed measure in the HH QRP. The MAP’s conditions of support include that, as a part of measure implementation, we provide guidance on the correct collection and calculation of the measure result, as well as guidance on public reporting Web sites explaining the impact of the specification changes on the measure result. The MAP’s conditions also

specify that CMS continue analyzing the proposed measure to investigate unexpected results reported in public comment. We intend to fulfill these conditions by offering additional training opportunities and educational materials in advance of public reporting, and by continuing to monitor and analyze the proposed measure. We provide private provider feedback reports as well as a Quarterly Quality Measure report that allow HHAs to track their measure outcomes for QI purposes. Aside from those reports, we conduct internal monitoring and evaluation of our measures to ensure that the measures are performing as they were intended to perform during the development of the measure. More information about the MAP’s recommendations for this measure is available at <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdIdentifier=id&ItemID=84452>.

We reviewed the NQF’s consensus endorsed measures and were unable to identify any home health measures that address changes in skin integrity related to pressure ulcers. Therefore, based on the evidence previously discussed, we are proposing to adopt the quality measure entitled, *Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury*, for the HH QRP beginning with the CY 2020 HH QRP. We plan to submit the proposed measure to the NQF for endorsement consideration as soon as feasible.

d. Data Collection

The data for this quality measure would be collected using the OASIS data set, which is currently submitted by HHAs through the Quality Improvement and Evaluation System (QIES) Assessment Submission and Processing (ASAP) System. The required items applicable to this measure are already reported by HHAs for patients and episodes of care meeting statutorily-defined criteria. While the inclusion of unstageable wounds in the proposed measure results in a measure calculation methodology that is different from the methodology used to calculate the current pressure ulcer measure, the data elements needed to calculate the proposed measure are already included on the OASIS data set. In addition, our proposal to eliminate duplicative data elements that were used in calculation of the current pressure ulcer measure will result in an overall reduced reporting burden for HHAs for the proposed measure. For more information on OASIS data set submission using the QIES ASAP System, we refer readers to <https://www.qts.com/>.

¹²⁴ Schwartz, M., Nguyen, K.H., Swinson Evans, T.M., Ignaczak, M.K., Thaker, S., and Bernard, S.L.: Development of a Cross-Setting Quality Measure for Pressure Ulcers: OY2 Information Gathering, Final Report. Centers for Medicare & Medicaid Services, November 2013. Available: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Development-of-a-Cross-Setting-Quality-Measure-for-Pressure-Ulcers-Information-Gathering-Final-Report.pdf>.

¹²⁵ Schwartz, M., Ignaczak, M.K., Swinson Evans, T.M., Thaker, S., and Smith, L.: The Development of a Cross-Setting Pressure Ulcer Quality Measure: Summary Report on November 15, 2013, Technical Expert Panel Follow-Up Webinar. Centers for Medicare & Medicaid Services, January 2014. Available: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Development-of-a-Cross-Setting-Pressure-Ulcer-Quality-Measure-Summary-Report-on-November-15-2013-Technical-Expert-Pa.pdf>.

For technical information about this proposed measure, including information about the measure calculation and the standardized patient assessment data elements used to calculate this measure, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking*, available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html>.

We are proposing that HHAs would begin reporting the proposed pressure ulcer measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, which will replace the current pressure ulcer measure, with data collection beginning with respect to admissions and discharges occurring on or after January 1, 2019.

We are inviting public comment on our proposal to remove the current pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), and replace it with a modified version of that measure, entitled, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, beginning with the CY 2020 HH QRP.

2. Proposal To Address the IMPACT Act Domain of Functional Status, Cognitive Function, and Changes in Function and Cognitive Function: Application of Percent of Long-Term Care Hospital Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631)

a. Measure Background

Sections 1899B(d)(1)(B) of the Act requires that no later than the specified application date (which under section 1899B(a)(1)(E)(ii) is January 1, 2019 for HHAs, and October 1, 2016 for SNFs, IRFs and LTCHs), the Secretary specify a quality measure to address the domain of “Functional status, cognitive function, and changes in function and cognitive function.” We propose to adopt the measure, Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631) for the HH QRP, beginning with the CY 2020 program year. This is a process measure that reports the percentage of patients with an admission and discharge functional assessment and treatment goal that addresses function. The treatment goal provides evidence that a care plan with

a goal has been established for the HH patient.

The National Committee on Vital and Health Statistics’ Subcommittee on Health,¹²⁶ noted that “information on functional status is becoming increasingly essential for fostering healthy people and a healthy population. Achieving optimal health and well-being for Americans requires an understanding across the life span of the effects of people’s health conditions on their ability to do basic activities and participate in life situations in other words, their functional status.” This is supported by research showing that patient and resident functioning is associated with important outcomes such as discharge destination and length of stay in inpatient settings,¹²⁷ as well as the risk of nursing home placement and hospitalization of older adults living in the community.¹²⁸ For example, many patients who utilize HH services may be at risk for a decline in function due to limited mobility and ambulation.¹²⁹ Thus, impairment in function activities such as self-care and mobility is highly prevalent in HH patients. For example, in 98 percent of the over six million HH episodes in 2015, the patient had at least one limitation or was not completely independent in self-care activities such as grooming, upper and lower body dressing, bathing, toilet hygiene, and/or feeding/eating.¹³⁰

The primary goal of home health care is to provide restorative care when improvement is expected, maintain function and health status if improvement is not expected, slow the rate of functional decline to avoid institutionalization in an acute or post-acute setting, and/or facilitate transition to end-of-life care as appropriate.^{131 132}

¹²⁶ Subcommittee on Health National Committee on Vital and Health Statistics, “Classifying and Reporting Functional Status” (2001).

¹²⁷ Reistetter T.A., Graham J.E., Granger C.V., Deutsch A., Ottenbacher K.J. Utility of Functional Status for Classifying Community Versus Institutional Discharges after Inpatient Rehabilitation for Stroke. *Archives of Physical Medicine and Rehabilitation*, 2010; 91:345–350.

¹²⁸ Miller E.A., Weissert W.G. Predicting Elderly People’s Risk for Nursing Home Placement, Hospitalization, Functional Impairment, and Mortality: A Synthesis. *Medical Care Research and Review*, 57; 3: 259–297.

¹²⁹ Kortebein, P., Ferrando, A., Lombebeida, J., Wolfe, R., & Evans, W.J. (2007). Effect of 10 days of bed rest on skeletal muscle in health adults. *JAMA*; 297(16):1772–4.

¹³⁰ Kortebein, P., Ferrando, A., Lombebeida, J., Wolfe, R., & Evans, W.J. (2007). Effect of 10 days of bed rest on skeletal muscle in health adults. *JAMA*; 297(16):1772–4.

¹³¹ Riggs, J. S. & Madigan, E. A. (2012). Describing variation in home health care episodes for patients with heart failure. *Home Health Care Management and Practice*, 24(3): 146–152.

Home health care can positively impact functional outcomes. In stroke patients, home-based rehabilitation programs administered by home health clinicians significantly improved ADL function and gait performance.¹³³ Home health services, delivered by a registered nurse, positively impacted patient Quality of Life (QOL) and clinical outcomes, including significant improvement in dressing lower body, bathing, meal preparation, shopping, and housekeeping. For some home health patients, achieving independence within the living environment and improved community mobility might be the goal of care. For others, the goal of care might be to slow the rate of functional decline to avoid institutionalization.¹³⁴

Patients’ functional status is associated with important patient outcomes, so measuring and monitoring the patients’ extent of engaging in self-care and mobility is valuable. Functional decline among the elderly;¹³⁵ and chronic illness comorbidities, such as chronic pain among the older adult population^{136 137} are associated with decreases in self-sufficiency and patient activation (defined as the patient’s knowledge and confidence in self-managing their health). Impaired mobility, frailty, and low physical activity are associated with institutionalization,¹³⁸ higher risk of

¹³² Ellenbecker, C.H., Samia, L., Cushman, M.J., & Alster, K (2008). Patient safety and quality: an evidence-based handbook for nurses. Rockville (MD): agency for healthcare research and quality (US); 2008 Apr. Chapter 13.

¹³³ Asiri, F. Y., Marchetti, G. F., Ellis, J. L., Otis, L., Sparto, P. J., Watzlaf, V., & Whitney, S. L. (2014). Predictors of functional and gait outcomes for persons poststroke undergoing home-based rehabilitation. *Journal of Stroke and Cerebrovascular Diseases: The Official Journal of National Stroke Association*, 23(7), 1856–1864. <https://doi.org/10.1016/j.jstrokecerebrovasdis.2014.02.025>.

¹³⁴ Ellenbecker, C.H., Samia, L., Cushman, M.J., & Alster, K (2008). Patient safety and quality: an evidence-based handbook for nurses. Rockville (MD): agency for healthcare research and quality (US); 2008 Apr. Chapter 13.

¹³⁵ Gleason, K. T., Tanner, E. K., Boyd, C. M., Saczynski, J. S., & Szanton, S. L. (2016). Factors associated with patient activation in an older adult population with functional difficulties. *Patient Education and Counseling*, 99(8), 1421–1426. <https://doi.org/10.1016/j.pec.2016.03.011>.

¹³⁶ Roberts AR, Betts Adams K, Beckett & Warner C. (2016). Effects of chronic illness on daily life and barriers to self-care for older women: a mixed-methods exploration. *J Women Aging*, Jul 25:1–11.

¹³⁷ Wu, J.-R., Lennie, T. A., & Moser, D. K. (2016). A prospective, observational study to explore health disparities in patients with heart failure-ethnicity and financial status. *European Journal of Cardiovascular Nursing: Journal of the Working Group on Cardiovascular Nursing of the European Society of Cardiology*. <https://doi.org/10.1177/1474515116641296>.

¹³⁸ Hajek, A., Brettschneider, C., Lange, C., Posselt, T., Wiese, B., Steinmann, S., Weyerer, S.,

falls and falls-related hip fracture and death,^{139 140} greater risk of undernutrition,¹⁴¹ higher rates of inpatient admission from the emergency department,¹⁴² and higher prevalence of hypertension and diabetes.¹⁴³

In addition, the assessment of functional ability and provision of treatment plans directed toward improving or maintaining functional ability could impact health care costs. Providing comprehensive home health care, which includes improving or maintaining functional ability for frail elderly adults, can reduce the likelihood of hospital readmissions or emergency department visits, leading to reduced health care service expenditures.^{144 145 146} Reducing preventable rehospitalizations, which made up approximately 17 percent of Medicare's \$102.6 billion in 2004

hospital payments, creates the potential for large health care cost savings.^{147 148}

Further, improving and maintaining functional ability in individuals with high needs, defined as those with three or more chronic conditions, may also account for an increase in healthcare savings. Adults with three or more chronic conditions have nearly four times the average annual per-person spending for health care services and prescription medications than the average for all U.S. adults, and high needs adults with limitations in their ability to perform ADLs, have even higher average annual health care expenditures.¹⁴⁹ High needs individuals with functional limitations spend, on average, \$21,021 on annual health care services, whereas the average annual health care expenditures for all U.S. adults are approximately \$4,845.¹⁴⁵

b. Measure Importance

The majority of individuals who receive PAC services, including care provided by HHAs, SNFs, IRFs, and LTCHs, have functional limitations, and many of these individuals are at risk for further decline in function due to limited mobility and ambulation.¹⁵⁰ The patient populations treated by HHAs, SNFs, IRFs, and LTCHs vary in terms of their functional abilities. For example, for home health patients, achieving independence within the home environment and promoting community mobility may be the goal of care. For other home health patients, the goal of care may be to slow the rate of functional decline in order to allow the person to remain at home and avoid institutionalization.¹⁵¹ The clinical practice guideline *Assessment of Physical Function*¹⁵² recommends that

clinicians document functional status at baseline and over time to validate capacity, decline, or progress. Therefore, assessment of functional status at admission and discharge, as well as establishing a functional goal for discharge as part of the care plan is an important aspect of patient or resident care across PAC settings.

Currently, functional assessment data are collected by all four PAC providers, yet data collection has employed different assessment instruments, scales, and item definitions. The data cover similar topics, but are not standardized across PAC settings. The different sets of functional assessment items coupled with different rating scales makes communication about patient and resident functioning challenging when patients and residents transition from one type of setting to another. Collection of standardized functional assessment data across HHAs, SNFs, IRFs, and LTCHs using common data items would establish a common language for patient and resident functioning, which may facilitate communication and care coordination as patients and residents transition from one type of provider to another. The collection of standardized functional status data may also help improve patient functioning during an episode of care by ensuring that basic daily activities are assessed for all PAC residents at the start and end of care, and that at least one functional goal is established.

The functional assessment items included in the proposed functional status quality measure were originally developed and tested as part of the Post-Acute Care Payment Reform Demonstration version of the Continuity Assessment Record and Evaluation (CARE) Item Set, which was designed to standardize the assessment of a person's status, including functional status, across acute and post-acute settings (HHAs, SNFs, IRFs, and LTCHs). The functional status items on the CARE Item Set are daily activities that clinicians typically assess at the time of admission and/or discharge to determine patient or resident needs, evaluate patient or resident progress, and prepare patients, residents, and their families for a transition to home or to another setting. The development of the CARE Item Set and a description and rationale for each item is described in a report entitled "The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set:

York (NY): Springer Publishing Company; 2012. p. 89–103.

Werle, J., Pentzek, M., Fuchs, A., Stein, J., Luck, T., Bickel, H., Mösch, E., Wagner, M., Jessen, F., Maier, W., Scherer, M., Riedel-Heller, S.G., König, H.H., & AgeCoDe Study Group. (2015). Longitudinal Predictors of Institutionalization in Old Age. *PLoS One*, 10(12):e0144203.

¹³⁹ Akahane, M., Maeyashiki, A., Yoshihara, S., Tanaka, Y., & Imamura, T. (2016). Relationship between difficulties in daily activities and falling: loco-check as a self-assessment of fall risk. *Interactive Journal of Medical Research*, 5(2), e20. <https://doi.org/10.2196/ijmr.5590>.

¹⁴⁰ Zaslavsky, O., Zelber-Sagi, S., Gray, S. L., LaCroix, A. Z., Brunner, R. L., Wallace, R. B., . . . Woods, N. F. (2016). Comparison of Frailty Phenotypes for Prediction of Mortality, Incident Falls, and Hip Fracture in Older Women. *Journal of the American Geriatrics Society*, 64(9), 1858–1862. <https://doi.org/10.1111/jgs.14233>.

¹⁴¹ van der Pols-Vijlbrief, R., Wijnhoven, H. A. H., Bosmans, J. E., Twisk, J. W. R., & Visser, M. (2016). Targeting the underlying causes of undernutrition. Cost-effectiveness of a multifactorial personalized intervention in community-dwelling older adults: A randomized controlled trial. *Clinical Nutrition* (Edinburgh, Scotland). <https://doi.org/10.1016/j.clnu.2016.09.030>.

¹⁴² Hominick, K., McLeod, V., & Rockwood, K. (2016). Characteristics of older adults admitted to hospital versus those discharged home, in emergency department patients referred to internal medicine. *Canadian Geriatrics Journal: CGJ*, 19(1), 9–14. <https://doi.org/10.5770/cgj.19.195>.

¹⁴³ Halaweh, H., Willen, C., Grimby-Ekman, A., & Svantesson, U. (2015). Physical activity and health-related quality of life among community dwelling elderly. *J Clin Med Res*, 7(11), 845–52.

¹⁴⁴ Hirth, V., Baskins, J., & Dever-Bumba, M. (2009). Program of all-inclusive care (PACE): Past, present, and future. *Journal of the American Medical Directors Association*, 10, 155–160.

¹⁴⁵ Mukamel, D. B., Fortinsky, R. H., White, A., Harrington, C., White, L. M., & Ngo-Metzger, Q. (2014). The policy implications of the cost structure of home health agencies. *Medicare & Medicaid Research Review*, 4(1). <https://doi.org/10.5600/mmrr2014-004-01-a03>.

¹⁴⁶ Meunier, M. J., Brant, J. M., Audet, S., Dickerson, D., Gransbery, K., & Cierns, E. L. (2016). Life after PACE (Program of All-Inclusive Care for the Elderly): A retrospective/prospective, qualitative analysis of the impact of closing a nurse practitioner centered PACE site. *Journal of the American Association of Nurse Practitioners*. <https://doi.org/10.1002/2327-6924.12379>.

¹⁴⁷ Jencks, S.F., Williams, M.V., and Coleman, E.A. (2009). Rehospitalizations among patients in the Medicare fee-for-service program. *New England Journal of Medicine*; 360(14):1418–28.

¹⁴⁸ Tao, H., Ellenbecker, C. H., Chen, J., Zhan, L., & Dalton, J. (2012). The influence of social environmental factors on rehospitalization among patients receiving home health care services. *ANS. Advances in Nursing Science*, 35(4), 346–358. <https://doi.org/10.1097/ANS.0b013e318271d2ad>.

¹⁴⁹ Hayes, S.L., Salzberg, C.A., McCarthy, D., Radley, DC, Abrams, M.K., Shah, T., and Anderson, G.F. (2016). High-Need, High-Cost Patients: Who are they and how do they use health care—A population-based comparison of demographics, health care use, and expenditures. *The Commonwealth Fund*.

¹⁵⁰ Kortebein P, Ferrando A, Lombebeida J, Wolfe R, Evans WJ. Effect of 10 days of bed rest on skeletal muscle in health adults. *JAMA*; 297(16):1772–4.

¹⁵¹ Ellenbecker CH, Samia L, Cushman MJ, Alster K. Patient safety and quality in home health care. *Patient Safety and Quality: An Evidence-Based Handbook for Nurses*. Vol 1.

¹⁵² Kresevic DM. Assessment of physical function. In: Boltz M, Capezuti E, Fulmer T, Zwicker D, editor(s). *Evidence-based geriatric nursing protocols for best practice*. 4th ed. New

Volume 1 of 3.”¹⁵³ Reliability and validity testing were conducted as part of CMS’s Post-Acute Care Payment Reform Demonstration (PAC-PRD), and we concluded that the functional status items have acceptable reliability and validity. Testing for the functional assessment items concluded that the items were able to evaluate all patients on basic self-care and mobility activities, regardless of functional level or PAC setting. A description of the testing methodology and results are available in several reports, including the report entitled “The Development and Testing of the Continuity Assessment Record And Evaluation (CARE) Item Set: Final Report On Reliability Testing: Volume 2 of 3”¹⁵⁴ and the report entitled “The Development and Testing of The Continuity Assessment Record And Evaluation (CARE) Item Set: Final Report on Care Item Set and Current Assessment Comparisons: Volume 3 of 3.”¹⁵⁵ These reports are available on our Post-Acute Care Quality Initiatives Web page at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html>.

Additional testing of these functional assessment items was conducted in a small field test occurring in 2016–2017, capturing data from 12 HHAs. Preliminary data results yielded moderate to substantial reliability for the self-care and mobility data items. More information about testing design and results can be found at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/OASIS-Data-Sets.html>. The functional status quality measure we are proposing to adopt beginning with the CY 2020 HH QRP is a process quality measure that is an application of the NQF-endorsed quality measure, the Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631). This quality measure reports the percent of patients with both an admission and a discharge functional assessment and a functional treatment goal.

This process measure requires the collection of admission and discharge functional status data by clinicians using standardized patient assessment

data elements, which assess specific functional activities, such as self-care and mobility activities. The self-care and mobility function activities are coded using a 6-level rating scale that indicates the resident’s level of independence with the activity at both admission and discharge. A higher score indicates more independence. These functional assessment data elements will be collected at Start or Resumption of Care (SOC/ROC) and discharge.

For this quality measure, there must be documentation at the time of admission (SOC) that at least one activity performance (function) goal is recorded for at least one of the standardized self-care or mobility function items using the 6-level rating scale. This indicates that an activity goal(s) has been established. Following this initial assessment, the clinical best practice would be to ensure that the patient’s care plan reflected and included a plan to achieve such activity goal(s). At the time of discharge, goal setting and establishment of a care plan to achieve the goal, is reassessed using the same 6-level rating scale, allowing for the ability to evaluate success in achieving the patient’s activity performance goals.

To the extent that a patient has an unplanned discharge, for example, transfer to an acute care facility, the collection of discharge functional status data may not be feasible. Therefore, for patients with unplanned discharges, admission functional status data and at least one treatment goal must be reported, but discharge functional status data are not required to be reported.

c. Stakeholder Feedback

Our measures contractor convened a TEP on October 17, and October 18, 2016. The TEP was composed of a diverse group of stakeholders with HH, PAC, and functional assessment expertise. The panel provided input on the technical specifications of this proposed measure, including the feasibility of implementing the measure, as well as the overall measure of reliability and validity. The TEP additionally provided feedback on the clinical assessment items used to calculate the measure. The TEP reviewed the measure “Percent of Long-Term Care Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF 2631)” for potential application to the home health setting. Overall they were supportive of a functional process measure, noting it could have the positive effect of focusing clinician attention on functional status and goals. A summary

of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Videos Web page at <https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/post-acute-care-quality-initiatives/impact-act-of-2014/impact-act-downloads-and-videos.html>.

We also solicited stakeholder feedback on the development of this measure through a public comment period held from November 4, 2016 through December 5, 2016. Several stakeholders and organizations supported this measure for implementation and for measure standardization. Some commenters also provided feedback on the standardized patient assessment data elements used to calculate the proposed quality measure. Commenters offered suggestions, including providing education regarding the difference in measure scales for the standardized items relative to current OASIS functional items, and guidance on the type of clinical staff input needed to appropriately complete new functional assessment items. Commenters also addressed the feasibility of collecting data for the individual standardized self-care and mobility items in the home health setting. Finally, commenters noted the importance of appropriate goal setting when functional improvement for a patient may not be feasible. The public comment summary report for the proposed measure is available on the CMS Web site at <https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/post-acute-care-quality-initiatives/impact-act-of-2014/impact-act-downloads-and-videos.html>.

The NQF-convened MAP met on December 14 and 15, 2016, and provided input on the use of this proposed measure in the HH QRP. The MAP recommended “conditional support for rulemaking” for this measure. MAP members noted the measure would drive care coordination and improve transitions by encouraging the use of standardized functional assessment items across PAC settings, but recommended submission to the NQF for endorsement to include the home health setting. More information about the MAP’s recommendations for this measure is available at http://www.qualityforum.org/Publications/2017/02/MAP_2017_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx.

We reviewed the NQF’s consensus endorsed measures and were unable to identify any home health measures that address functional assessment, and treatment goals that address function.

¹⁵³ Barbara Gage et al., “The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set” (RTI International, 2012).

¹⁵⁴ Ibid.

¹⁵⁵ Ibid.

There are five functional measures in home health that assess functional activities: (1) Improvement in Ambulation/Locomotion (NQF #0167); (2) Improvement in Bathing (NQF #0174); (3) Improvement in Bed Transfer (NQF #0175); (4) Improvement in Management of Oral Medications (NQF #0176); and (5) Improvement in Pain Interfering with Activity (NQF #0177). Our review determined that these setting-specific measures are not appropriate to meet the specified IMPACT Act domain as they do not include standardized items or are not included for various other PAC populations. Specifically:

- The items used to collect data for the current home health measures are less specific, leading to broader measure results, whereas the standardized patient assessment data items used for the proposed measure assess core activities such as rolling in bed, walking a specified distance, or wheelchair capability.
- The item coding responses are more detailed when compared to the non-standardized OASIS item responses, allowing for more granular data for the measure.
- The proposed functional measure will capture a patient's discharge goal at admission into home health; this detail is not captured in the existing endorsed HH function measures.

Therefore, based on the evidence discussed above, we are proposing to adopt the quality measure entitled, Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631), for the HH QRP beginning with the CY 2020 HH QRP. We plan to submit the proposed measure to the NQF for endorsement consideration as soon as is feasible.

For technical information about this proposed measure, including information about the measure calculation and the standardized patient assessment data elements used to calculate this measure, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking*, available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html>.

d. Data Collection

For purposes of assessment data collection, we propose to add new functional status items to the OASIS, to

be collected at SOC/ROC and discharge. These items would assess specific self-care and mobility activities, and would be based on functional items included in the PAC-PRD version of the CARE Item Set. More information pertaining to item testing is available on our Post-Acute Care Quality Initiatives Web page at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html>.

To allow HHAs to fulfill the requirements of the Home Health Agency Conditions of Participation (HHA CoPs) (82 FR 4504), we are proposing to add a subset of the functional assessment items to the OASIS, with collection of these items at Follow-Up (FU). The collection of these assessment items at FU by HHAs will allow them to fulfill the requirements outlined in the HHA CoPs that suggest that the collection of a patient's current health, including functional status, be collected on the comprehensive assessment.

These new functional status items are standardized across PAC settings and support the proposed standardized measure. They are organized into two functional domains: Self-Care and Mobility. Each domain includes dimensions of these functional constructs that are relevant for home health patients. The proposed function items that we would add to the OASIS for purposes of the calculation of this proposed quality measure do not duplicate existing items currently collected in that assessment instrument for other purposes. The current OASIS function items evaluate current ability, whereas the proposed functional items would evaluate an individual's usual performance at the time of admission and at the time of discharge for goal setting purposes. Additionally, there are several key differences between the existing and new proposed function items that may result in variation in the patient assessment results including: (1) The data collection and associated data collection instructions; (2) the rating scales used to score a resident's level of independence; and (3) the item definitions. A description of these differences is provided with the measure specifications available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html>.

Because of the differences between the current function assessment items (OASIS C-2) and the proposed function assessment items that we would collect for purposes of calculating the proposed

measure, we would require that HHAs submit data on both sets of items. Data collection for the new proposed function items do not substitute for the data collection under the current OASIS ADL and IADL items. Although providers will collect on the proposed function assessment items as well as the current assessment items, for reasons previously described, we believe these items are not duplicative. However, we request comment on opportunities to streamline reporting to avoid duplication and minimize burden.

We are proposing that data for the proposed quality measure would be collected through the OASIS, which HHAs currently submit through the QIES ASAP system. We refer readers to section V.F.2 of this proposed rule for more information on the proposed data collection and submission timeline for this proposed quality measure. If this measure is finalized, we intend to provide initial confidential feedback to home health agencies, prior to the public reporting of this measure.

We invite public comment on our proposal to adopt the measure, Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).

3. Proposal To Address the IMPACT Act Domain of "Incidence of Major Falls" Measure: Percent of Residents Experiencing One or More Falls With Major Injury

a. Measure Background

Sections 1899B(c)(1)(D) of the Act requires that no later than the specified application date (which under section 1899B(a)(1)(E)(i)(IV) is January 1, 2019 for HHAs, and October 1, 2016 for SNFs, IRFs and LTCHs), the Secretary specify a measure to address the domain of incidence of major falls, including falls with major injury. We propose to adopt the measure, Application of Percent of Residents Experiencing One or More Falls with Major Injury (NQF #0674), for which we would begin to collect data on January 1, 2019 for the CY 2020 HH QRP to meet this requirement. This proposed outcome measure reports the percentage of residents who have experienced falls with major injury during episodes ending in a 3-month period.

b. Measure Importance

Falls affect an estimated 6 to 12 million older adults each year and are the leading cause of both fatal injury

and nonfatal hospital admissions.^{156 157} Within the home health population, the risk of falling is significant as approximately one third of individuals over the age of 65 experienced at least one fall annually.¹⁵⁸ Major fall-related injuries among older community-dwelling adults are a growing health concern within the United States^{159 160} because they can have high medical and cost implications for the Medicare community.¹⁶¹ In 2013, the direct medical cost for falls in older adults was \$34 billion¹⁶² and is projected to increase to over \$101 billion by 2030 due to the aging population.¹⁶³

Evidence from various studies indicates that implementing effective fall prevention interventions and minimizing the impact of falls that do occur reduces overall costs, emergency department visits, hospital readmissions, and overall Medicare resource utilization.^{164 165 166 167} In the

2006 Home Assessments and Modification study, a home visit by an occupational therapist or home care worker to identify and mitigate potential home hazards and risky behavior, resulted in a 46 percent reduction in fall rates for those receiving the intervention compared to controls.¹⁶⁸ Overall, patients participating in interventions experienced improved quality of life due to reduced morbidity, improved functional ability and mobility, reduced number of falls and injurious falls, and a decrease in the fear of falling.^{169 170} Falls also represent a significant cost burden to Medicare. Each year, 2.8 million older people are treated in Emergency Departments for fall related injuries and over 800,000 require hospitalization.¹⁷¹ Adjusted to 2015 dollars, nationally, direct medical costs for non-fatal fall related injuries in older adults were over \$31.3 billion.¹⁷² Additional health care costs (in 2010 dollars) can range from \$3,500 for a fall without serious injury to \$27,000 for a fall with a serious injury.¹⁷³ Between 1988 and 2005, fractures accounted for 84 percent of hospitalizations for fall-related injuries among older adults.¹⁷⁴ Researchers evaluated the cost of fall-related hospitalizations among older adults using the 2011 Texas Hospital Inpatient Discharge Data and determined that the average cost for fall-related hip fractures was \$61,715 for individuals 50 and older living in

metropolitan areas and \$55,366 for those living nonmetropolitan areas.¹⁷⁵

To meet the IMPACT Act provision requiring the development of a standardized quality measure for the domain of Incidence of Major Falls (sections 1899B(c)(1)(D) of the Act), we developed the proposed standardized measure, The Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674). This quality measure is NQF-endorsed and has been successfully implemented in the Nursing Home Quality Initiative for nursing facility long-stay residents since 2011, demonstrating the measure is feasible, appropriate for assessing PAC quality of care, and could be used as a platform for standardized quality measure development. This quality measure is standardized across PAC settings and contains items that are collected uniformly in each setting's assessment instruments (that is, MDS, IRF-PAI, and LCDS). Further, an application of the quality measure was adopted for use in the LTCH QRP in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50874 through 50877), revised in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50290), and adopted to fulfill IMPACT Act requirements in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49736 through 49739). Data collection began in April 1, 2016 for LTCHs, and October 1, 2016 for SNFs and IRFs.

More information on the NQF-endorsed quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) is available at <http://www.qualityforum.org/QPS/0674>.

c. Stakeholder Feedback

A TEP convened by our measure development contractor provided input on the technical specifications of an application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674), including the feasibility of implementing the measure across PAC settings. The TEP was supportive of the implementation of this measure across PAC settings and was also supportive of our efforts to standardize this measure for cross-setting development. More information about this TEP can be found at <https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/post-acute-care-quality-initiatives/impact-act-of-2014/impact-act-downloads-and-videos.html>.

¹⁷⁵ Towne, S. D., Ory, M. G., & Smith, M. L. (2014). Cost of fall-related hospitalizations among older adults: environmental comparisons from the 2011 Texas hospital inpatient discharge data. *Population Health Management*, 17(6), 351–356.

¹⁵⁶ Bohl, A. A., Phelan, E. A., Fishman, P. A., & Harris, J. R. (2012). How are the costs of care for medical falls distributed? The costs of medical falls by component of cost, timing, and injury severity. *The Gerontologist*, 52(5): 664–675.

¹⁵⁷ National Council on Aging (2015). Falls Prevention Fact Sheet. Retrieved from https://www.ncoa.org/wp-content/uploads/Fact-Sheet_Falls-Prevention.pdf.

¹⁵⁸ Avin G., K., Hanke A., T., Kirk-Sanchez, N., McDonough M., C., Shubert E., T., Hardage, J., & Hartley, G. (2015). Management of Falls in Community-Dwelling Older Adults: Clinical Guidance Statement From the Academy of Geriatric Physical Therapy of the American Physical Therapy Association. *Physical Therapy*, 95(6), 815–834. doi:10.2522/ptj.20140415.

¹⁵⁹ Hester, A. L. & Wei, F. (2013). Falls in the community: state of the science. *Clinical Interventions in Aging*, 8:675–679.

¹⁶⁰ Orces, C. H. & Alamgir, H. (2014). Trends in fall-related injuries among older adults treated in emergency departments in the USA. *Injury Prevention*, 20: 421–423.

¹⁶¹ Liu, S. W., Obermeyer, Z., Chang, Y., & Shankar, K. N. (2015). Frequency of ED revisits and death among older adults after a fall. *American Journal of Emergency Medicine*, 33(8), 1012–1018. doi:10.1016/j.ajem.2015.04.023.

¹⁶² Centers for Disease Control and Prevention (2015b). Important facts about falls. <http://www.cdc.gov/homeandrecreationalafety/falls/adultfalls.html>. Accessed April 19, 2016.

¹⁶³ Houry, D., Florence, C., Bladwin, G., Stevens, J., & McClure, R. (2015). The CDC Injury Center's response to the growing public health problem of falls among older adults. *American Journal of Lifestyle Medicine*, 10(1), 74–77.

¹⁶⁴ Bamgbade, S., & Dearmon, V. (2016). Fall prevention for older adults receiving home healthcare. *Home Healthcare Now*, 34(2), 68–75.

¹⁶⁵ Carande-Kulis, V., Stevens, J. A., Florence, C. S., Beattie, B. L., & Arias, I. (2015). A cost-benefit analysis of three older adult fall prevention interventions. *Journal of Safety Research*, 52, 65–70. doi:10.1016/j.jsr.2014.12.007.

¹⁶⁶ Cohen, A. M., Miller, J., Shi, X., Sandhu, J., & Lipsitz, A. (2015). Prevention program lowered the risk of falls and decreased claims for long-term care services among elder participants. *Health Affairs*, 34(6), 971–977.

¹⁶⁷ Howland, J., Shankar, K. N., Peterson, E. W., & Taylor, A. A. (2015). Savings in acute care costs

if all older adults treated for fall-related injuries completed matter of balance. *Injury Epidemiology*, 2(25), 1–7.

¹⁶⁸ Pighills AC, Torgerson DJ, Sheldon TA, Drummond AE, Bland JM. Environmental assessment and modification to prevent falls in older people. *Journal of the American Geriatrics Society*. 2011;59(1):26–33.

¹⁶⁹ Chase, C. A., Mann, K., Wasek, S., & Arbesman, M. (2012). Systematic review of the effect of home modification and fall prevention programs on falls and the performance of community-dwelling older adults. *American Journal of Occupational Therapy*, 66(3), 284–291.

¹⁷⁰ Patil, R., Uusi-Rasi, K., Tokola, K., Karinkanta, S., Kannus, P., & Sievanen, H. (2015). Effects of a Multimodal Exercise Program on Physical Function, Falls, and Injuries in Older Women: A 2-Year Community-Based, Randomized Controlled Trial. *Journal of the American Geriatrics Society*, 63(7), 1306–1313.

¹⁷¹ Centers for Disease Control and Prevention, National Center for Injury Prevention and Control. Web-based Injury Statistics Query and Reporting System (WISQARS) [online]. Accessed August 5, 2016.

¹⁷² Burns ER, Stevens JA, Lee R. The direct costs of fatal and non-fatal falls among older adults—United States. *J Safety Res* 2016;58:99–103.

¹⁷³ Wu S, Keeler EB, Rubenstein LZ, Maglione MA, Shekelle PG. A cost-effectiveness analysis of a proposed national falls prevention program. *Clin Geriatr Med*. 2010;26(4): 751–66.

¹⁷⁴ Orces, C. H. & Alamgir, H. (2014). Trends in fall-related injuries among older adults treated in emergency departments in the USA. *Injury Prevention*, 20: 421–423.

In addition, we solicited public comment on this measure from September 19, 2016 through October 14, 2016. Overall, commenters were generally supportive of the measure, but raised concerns about the attribution given that home health clinicians are not present in the home at all times and recommended risk-adjusting the measure. The summary of this public comment period can be found at <https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/post-acute-care-quality-initiatives/impact-act-of-2014/impact-act-downloads-and-videos.html>.

Finally, we presented this measure to the NQF-convened MAP on December 14, 2016. The MAP conditionally supported the use of an application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) in the HH QRP as a cross-setting quality measure. The MAP highlighted the clinical significance of falls with major injury, while noting potential difficulties in collecting falls data and more limited actionability in the HH setting. The MAP suggested that CMS explore stratification of measure rates by referral origin when public reporting. More information about the MAP's recommendations for this measure is available at http://www.qualityforum.org/Publications/2017/02/MAP_2017_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx. We are inviting public comment on the stratification of the proposed measure, specifically on the measure rates for public reporting. The quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) is not currently endorsed for the HH setting. We reviewed the NQF's consensus endorsed measures and were unable to identify any NQF-endorsed cross-setting quality measures for that setting that are focused on falls with major injury. We found one falls-related measure in home health titled, Multifactor Fall Risk

Assessment Conducted for All Patients Who Can Ambulate (NQF #0537).

We are also aware of one NQF-endorsed measure, Falls with Injury (NQF #0202), which is a measure designed for adult acute inpatient and rehabilitation patients capturing "all documented patient falls with an injury level of minor or greater on eligible unit types in a calendar quarter, reported as injury falls per 100 days."¹⁷⁶ After careful review, we have determined that these measures are not appropriate to meet the IMPACT Act domain of incidence of major falls. Specifically:

- NQF #0202 includes minor injuries in the numerator definition. Including all falls in an outcome measure could result in providers limiting activity for individuals at higher risk for falls.

- NQF #0537 is a process-based measure of HHAs' efforts to assess the risk for any fall, but not actual falls.

- Neither measure is standardized across PAC settings.

We are unaware of any other cross-setting quality measures for falls with major injury that have been endorsed or adopted by another consensus organization for the HH setting. Therefore, based on the evidence discussed above, we are proposing to adopt the quality measure entitled, An Application of the Measure Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674), for the HH QRP beginning with the CY 2020 HH QRP. We plan to submit the proposed measure to the NQF for endorsement consideration as soon as it is feasible.

d. Data Collection

For purposes of assessment data collection, we propose to add two new falls-related items to the OASIS. The proposed falls with major injury item used to calculate the proposed quality measure does not duplicate existing items currently collected in the OASIS. We propose to add two standardized items to the OASIS for collection at End of Care (EOC), which comprises the Discharge from Agency, Death at Home,

and Transfer to an Inpatient Facility time points: J1800 and J1900. The first item (J1800) is a gateway item that asks whether the patient has experienced any falls since admission/resumption of care (prior assessment). If the answer to J1800 is yes, the next item (J1900) asks for the number of falls with: (a) No injury, (b) injury (except major), and (c) major injury. The measure is calculated using data reported for J1900C (number of falls with major injury). This measure would be calculated at the time of discharge (see Section V.F.3 of this proposed rule). For technical information about this proposed measure, including information pertaining to measure calculation and the standardized patient assessment data element used to calculate this measure, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking*, available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html>.

We are proposing that data for the proposed quality measure would be collected through the OASIS, which HHAs currently submit through the QIES ASAP system. We refer readers to section V.I.4 of this proposed rule for more information on the proposed data collection and submission timeline for this proposed quality measure.

We are inviting public comments on our proposal to adopt an application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) for the CY 2020 HH QRP.

G. HH QRP Quality Measures and Measure Concepts Under Consideration for Future Years

We are inviting public comment on the importance, relevance, appropriateness, and applicability of each of the quality measures listed in Table 48 for use in future years in the HH QRP.

TABLE 48—HH QRP QUALITY MEASURES UNDER CONSIDERATION FOR FUTURE YEARS

IMPACT Act domain	Functional status, cognitive function, and changes in function and cognitive function
Measures	A. Application of NQF #2633—Change in Self-Care Score for Medical Rehabilitation Patients. B. Application of NQF #2634—Change in Mobility Score for Medical Rehabilitation Patients. C. Application of NQF #2635—Discharge Self-Care Score for Medical Rehabilitation Patients. D. Application of NQF #2636—Discharge Mobility Score for Medical Rehabilitation Patients.

¹⁷⁶ American Nurses Association (2014, April 9). Falls with injury. Retrieved from <http://www.qualityforum.org/QPS/0202>.

We are considering four measures that would assess a change in functional outcomes such as self-care and mobility across a HH episode. These measures would be standardized to measures finalized in other PAC quality reporting programs, such as the IRF QRP. We invite feedback on the importance, relevance, appropriateness, and applicability of these measure constructs.

Based on input from stakeholders, we have identified additional concept areas for potential future measure development for the HH QRP. These include claims-based within stay potentially preventable hospitalization measures. The potentially preventable within-stay hospitalization measures would look at the percentage of HH episodes in which patients were admitted to an acute care hospital or seen in an emergency department for a potentially preventable condition during an HH episode. We invite feedback on the importance, relevance, appropriateness, and applicability of these measure constructs.

In alignment with the requirements of the IMPACT Act to develop quality measures and standardize data for comparative purposes, we believe that evaluating outcomes across the post-acute settings using standardized data is an important priority. Therefore, in addition to proposing a process-based measure for the domain of “Functional status, cognitive function, and changes in function and cognitive function”, included in this year’s proposed rule, we also intend to develop outcomes-based quality measures, including functional status and other quality outcome measures to further satisfy this domain.

1. IMPACT Act Implementation Update

As a result of the input and suggestions provided by technical experts at the TEPs held by our measure developer, and through public comment, we are engaging in additional development work for two measures that would satisfy 1899B(c)(1)(E) of the Act, including performing additional testing. We intend to specify these measures under section 1899B(c)(1)(E) of the Act no later than January 1, 2019 and we intend to propose to adopt them for the CY 2021 HH QRP, with data collection beginning on or about January 1, 2020.

H. Proposed Standardized Patient Assessment Data

1. Proposed Standardized Patient Assessment Data Reporting for the CY 2019 HH QRP

Section 1895(b)(3)(B)(v)(IV)(bb) of the Act requires that for calendar years beginning on or after January 1, 2019, HHAs submit to the Secretary standardized patient assessment data required under section 1899B(b)(1) of the Act.

As we describe in more detail above, we are proposing that the current pressure ulcer measure, Application of Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), be replaced with the proposed pressure ulcer measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, beginning with the CY 2020 HH QRP. The current pressure ulcer measure will remain in the HH QRP until that time. Accordingly, for the requirement that HHAs report standardized patient assessment data for the CY 2019 HH QRP, we are proposing that the data elements used to calculate that measure meet the definition of standardized patient assessment data for medical conditions and co-morbidities under section 1899B(b)(1)(B)(iv) of the Act, and that the successful reporting of that data under section 1895(b)(3)(B)(v)(IV)(aa) of the Act for the beginning of the HH episode (for example, HH start of care/resumption of care), as well as the end of the HH episode (discharges) occurring during the first two quarters of CY 2018 would also satisfy the requirement to report standardized patient assessment data beginning with the CY 2019 HH QRP.

The collection of assessment data pertaining to skin integrity, specifically pressure related wounds, is important for multiple reasons. Clinical decision making, care planning, and quality improvement all depend on reliable assessment data collection. Pressure related wounds represent poor outcomes, are a serious medical condition that can result in death and disability, are debilitating and painful, and are often avoidable.

177 178 179 180 181 182 Pressure related

¹⁷⁷ Casey, G. (2013). “Pressure ulcers reflect quality of nursing care.” *Nurs N Z* 19(10): 20–24.

¹⁷⁸ Gorzoni, M.L. and S.L. Pires (2011). “Deaths in nursing homes.” *Rev Assoc Med Bras* 57(3): 327–331.

¹⁷⁹ Thomas, J.M., et al. (2013). “Systematic review: health-related characteristics of elderly hospitalized adults and nursing home residents associated with short-term mortality.” *J Am Geriatr Soc* 61(6): 902–911.

¹⁸⁰ White-Chu, E.F., et al. (2011). “Pressure ulcers in long-term care.” *Clin Geriatr Med* 27(2): 241–258.

wounds are considered healthcare acquired conditions.

As we note above, the data elements needed to calculate the current pressure ulcer measure are already included on the OASIS data set and reported by HHAs, and exhibit validity and reliability for use across PAC providers. Item reliability for these data elements was also tested for the nursing home setting during implementation of MDS 3.0. Testing results are from the RAND Development and Validation of MDS 3.0 project.¹⁸³ The RAND pilot test of the MDS 3.0 data elements showed good reliability and are applicable to the OASIS because the data elements tested are the same as those used in the OASIS Data Set. Across the pressure ulcer data elements, the average gold-standard nurse to gold-standard nurse kappa statistic was 0.905. The average gold-standard nurse to facility-nurse kappa statistic was 0.937. Data elements used to risk adjust this quality measure were also tested under this same pilot test, and the gold-standard to gold-standard kappa statistic, or percent agreement (where kappa statistic not available), ranged from 0.91 to 0.99 for these data elements. These kappa scores indicate “almost perfect” agreement using the Landis and Koch standard for strength of agreement.¹⁸⁴

The data elements used to calculate the current pressure ulcer measure received public comment on several occasions, including when that measure was proposed in the CY 2016 HH PPS (80 FR 68623). Further, they were discussed in the past by TEPs held by our measure development contractor on June 13 and November 15, 2013, and recently by a TEP on July 18, 2016. TEP members supported the measure and its cross-setting use in PAC. The report, Technical Expert Panel Summary Report: Refinement of the Percent of Patients or Residents with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678) Quality Measure for Skilled Nursing Facilities (SNFs), Inpatient Rehabilitation Facilities (HHAs), Long-Term Care Hospitals

¹⁸¹ Bates-Jensen BM. Quality indicators for prevention and management of pressure ulcers in vulnerable elders. *Ann Int Med*. 2001;135 (8 Part 2), 744–51.

¹⁸² Bennet, G, Dealy, C Posnett, J (2004). The cost of pressure ulcers in the UK, *Age and Aging*, 33(3):230–235.

¹⁸³ Saliba, D., & Buchanan, J. (2008, April). *Development and validation of a revised nursing home assessment tool: MDS 3.0*. Contract No. 500–00–0027/Task Order #2. Santa Monica, CA: Rand Corporation. Retrieved from <http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf>.

¹⁸⁴ Landis, R., & Koch, G. (1977, March). The measurement of observer agreement for categorical data. *Biometrics* 33(1), 159–174.

(LTCHs), and Home Health Agencies (HHAs), is available at and <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We are inviting public comment on this proposal.

2. Proposed Standardized Patient Assessment Data Reporting Beginning With the CY 2020 HH QRP

We describe below our proposals for the reporting of standardized patient assessment data by HHAs beginning with the CY 2020 HH QRP. LTCHs, IRFs, and SNFs are also required to report standardized patient assessment data through their applicable PAC assessment instruments, and they do so by responding to identical assessment questions developed for their respective settings using an identical set of response options (which incorporate an identical set of definitions and standards). HHAs would be required to report these data at admission (SOC/ROC) and discharge beginning on January 1, 2019, with the exception of three data elements (Brief Interview of Mental Status (BIMS), Hearing, and Vision) that will be required at SOC/ROC only, as described below. The BIMS, Hearing and Vision data elements would be assessed at SOC/ROC only due to the relatively stable nature of the types of cognitive function, hearing impairment, and vision impairment, making it unlikely that these assessments would change between the start and end of the HHA episode of care. Assessment of the BIMS, Hearing, and Vision data elements at EOC would introduce additional burden without improving the quality or usefulness of the data, and is deemed unnecessary. Following the initial reporting year (which would be based on 6 months of data) for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on a full calendar year of such data reporting.

In selecting the data elements described below, we carefully weighed the balance of burden in assessment-based data collection and aimed to minimize additional burden through the utilization of existing data in the assessment instruments. We also note that the patient and resident assessment instruments are considered part of the medical record and sought the inclusion of data elements relevant to patient care.

We also took into consideration the following factors for each data element: overall clinical relevance; ability to support clinical decisions, care

planning, and interoperable exchange to facilitate care coordination during transitions in care; and the ability to capture medical complexity and risk factors that can inform both payment and quality. In addition, the data elements had to have strong scientific reliability and validity; be meaningful enough to inform longitudinal analysis by providers; had to have received general consensus agreement for its usability; and had to have the ability to collect such data once but support multiple uses. Further, to inform the final set of data elements for proposal, we took into account technical and clinical subject matter expert review, public comment, and consensus input in which such principles were applied.

3. Proposed Standardized Patient Assessment Data by Category

a. Functional Status Data

We are proposing that the data elements that would be reported by HHAs to calculate the measure, Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631), as described in section V.F.2 would also meet the definition of standardized patient assessment data for functional status under section 1899B(b)(1)(B)(i) of the Act, and that the successful reporting of that data under section 1895(b)(3)(B)(v)(IV)(aa) of the Act would also satisfy the requirement to report standardized patient assessment data under section 1895(b)(3)(B)(v)(IV)(bb) of the Act. Details on the data used to calculate this measure is discussed in section V.F.2.

To further satisfy the requirements under section 1899B(b)(1)(B)(i) of the Act and specifically our efforts to achieve standardized patient assessment data pertaining to functional status, such as mobility and self-care at admission to a PAC provider and before discharge from a PAC provider, we are also proposing to adopt the functional status data elements that specifically address mobility and self-care as provided in the Act. These data elements are also used to calculate the function outcome measures implemented and/or proposed for implementation in three other post-acute quality reporting programs to which the IMPACT Act applies (Application of NQF #2633—Change in Self-Care Score for Medical Rehabilitation Patients; Application of NQF #2634—Change in Mobility Score for Medical Rehabilitation Patients; Application of NQF #2635—Discharge

Self-Care Score for Medical Rehabilitation Patients; and Application of NQF #2636—Discharge Mobility Score for Medical Rehabilitation Patients). To achieve standardization, we have implemented such data elements, or sub-sets of the items, into the other post-acute care patient/resident assessment instruments and we are proposing that they also meet the definition of standardized patient assessment data for functional status under section 1899B(b)(1)(B)(i) of the Act, and that the successful reporting of such data under section 1895(b)(3)(B)(v)(IV)(aa) of the Act would also satisfy the requirement to report standardized patient assessment data under section 1895(b)(3)(B)(v)(IV)(bb) of the Act. These data elements currently are collected in the Section GG: Functional Abilities and Goals located in current versions of the MDS and the IRF-PAI assessment instruments.

As previously described, these patient assessment data that assess for functional status are from the CARE Item Set. They were specifically developed for cross-setting application and are the result of consensus building and public input. Further, we received public comment and input. Their reliability and validity testing were conducted as part of CMS' Post-Acute Care Payment Reform Demonstration, and we concluded that the functional status items have acceptable reliability and validity. We refer the reader to section V.F.2 for a full description of the CARE Item Set and description of the testing methodology and results that are available in several reports. For more information about this quality measure and the data elements used to calculate it, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49739 through 49747), the FY 2016 IRF PPS final rule (80 FR 47100 through 47111), and the FY 2016 SNF PPS final rule (80 FR 46444 through 46453).

Therefore, we are proposing to adopt the functional status data elements that as for the CY 2020 HH QRP, HHAs would be required to report these data at SOC/ROC or discharge starting on January 1, 2019. This aligns with the required reporting timeframe for the CY 2020 HH QRP. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of data reporting beginning with July 1, 2019, through June 30, 2020 for the CY 2021 HH QRP.

We seek comment on this proposal.

b. Cognitive Function and Mental Status Data

Cognitive function and mental status in PAC patient and resident populations can be affected by a number of underlying conditions, including dementia, stroke, traumatic brain injury, side effects of medication, metabolic and/or endocrine imbalances, delirium, and depression.¹⁸⁵ The assessment of cognitive function and mental status by PAC providers is important because of the high percentage of patients and residents with these conditions,¹⁸⁶ and to improve quality of care. Symptoms of dementia may improve with pharmacotherapy, occupational therapy, or physical activity,^{187 188 189} and promising treatments for severe traumatic brain injury are currently being tested.¹⁹⁰ For older patients and residents diagnosed with depression, treatment options to reduce symptoms and improve quality of life include antidepressant medication and psychotherapy,^{191 192 193 194} and targeted services, such as therapeutic recreation, exercise, and restorative nursing, to

increase opportunities for psychosocial interaction.¹⁹⁵

Accurate assessment of cognitive function and mental status of patients and residents in PAC would be expected to have a positive impact on the National Quality Strategy's domains of patient and family engagement, patient safety, care coordination, clinical process/effectiveness, and efficient use of health care resources. For example, standardized assessment of cognitive function and mental status of patients and residents in PAC will support establishing a baseline for identifying changes in cognitive function and mental status (for example, delirium), anticipating the patient or resident's ability to understand and participate in treatments during a PAC stay, ensuring patient and resident safety (for example, risk of falls), and identifying appropriate support needs at the time of discharge or transfer. Standardized assessment data elements will enable or support clinical decision-making, early clinical intervention, as well as person-centered, high quality care through: Facilitating better care continuity and coordination; better data exchange and interoperability between settings; and longitudinal outcome analysis. Hence, reliable data elements assessing cognitive impairment and mental status are needed to initiate a care plan that can best manage a patient or resident's prognosis and reduce the possibility of adverse events.

i. Brief Interview for Mental Status (BIMS)

We are proposing that the data elements that comprise the Brief Interview for Mental Status meet the definition of standardized patient assessment data for cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act. The proposed data elements consist of seven BIMS questions that result in a cognitive function score. For more information on the BIMS, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking*, available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html>.

The BIMS is a performance-based cognitive assessment that assesses repetition, recall with and without

prompting, and temporal orientation. It was developed to be a brief screener to assess cognition, with a focus on learning and memory. Dementia and cognitive impairment are associated with long-term functional dependence and, consequently, poor quality of life, increased health care costs, and mortality.¹⁹⁶ This makes assessment of mental status and early detection of cognitive decline or impairment critical in the PAC setting. The intensity of routine nursing care is higher for patients and residents with cognitive impairment than for those without, and dementia is a significant variable in predicting readmission after discharge to the community from PAC providers.¹⁹⁷

The BIMS data elements are currently in use in two of the PAC assessments: The MDS 3.0 in SNFs and the IRF-PAI in IRFs. The BIMS was tested in the PAC PRD where it was found to have substantial to almost perfect agreement for inter-rater reliability (kappa range of 0.71 to 0.91) when tested in all four PAC settings.¹⁹⁸ Clinical and subject matter expert advisors working with our data element contractor agreed that the BIMS is feasible for use by PAC providers. Additionally, discussions during a TEP convened on April 6 and 7, 2016, demonstrated support for the BIMS. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data Technical Expert Panel Summary Report is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

To solicit additional feedback on the BIMS, we requested public comment from August 12 to September 12, 2016. Many commenters expressed support for use of the BIMS, noting that it is reliable, feasible to use across settings, and will provide useful information about patients and residents. These comments noted that the data collected through the BIMS will provide a clearer picture of patient or resident complexity, help with the care planning

¹⁹⁶ Agüero-Torres, H., Fratiglioni, L., Guo, Z., Viitanen, M., von Strauss, E., & Winblad, B. (1998). "Dementia is the major cause of functional dependence in the elderly: 3-year follow-up data from a population-based study." *Am J of Public Health* 88(10): 1452–1456.

¹⁹⁷ RTI International. *Proposed Measure Specifications for Measures Proposed in the FY 2017 LTCH QRP NPRM*. Research Triangle Park, NC. 2016.

¹⁹⁸ Gage B., Morley M., Smith L., et al. (2012). *Post-Acute Care Payment Reform Demonstration (Final report, Volume 2 of 4)*. Research Triangle Park, NC: RTI International.

¹⁸⁵ National Institute on Aging. (2014). *Assessing Cognitive Impairment in Older Patients. A Quick Guide for Primary Care Physicians*. Retrieved from <https://www.nia.nih.gov/alzheimers/publication/assessing-cognitive-impairment-older-patients>.

¹⁸⁶ Gage B., Morley M., Smith L., et al. (2012). *Post-Acute Care Payment Reform Demonstration (Final report, Volume 4 of 4)*. Research Triangle Park, NC: RTI International.

¹⁸⁷ Casey D.A., Antimisiaris D., O'Brien J. (2010). *Drugs for Alzheimer's Disease: Are They Effective? Pharmacology & Therapeutics*, 35, 208–11.

¹⁸⁸ Graff M.J., Vernooij-Dassen M.J., Thijssen M., Dekker J., Hoefnagels W.H., Rikkert M.G.O. (2006). *Community Based Occupational Therapy for Patients with Dementia and their Care Givers: Randomised Controlled Trial*. *BMJ*, 333(7580): 1196.

¹⁸⁹ Bherer L., Erickson K.I., Liu-Ambrose T. (2013). *A Review of the Effects of Physical Activity and Exercise on Cognitive and Brain Functions in Older Adults*. *Journal of Aging Research*, 657508.

¹⁹⁰ Giacino J.T., Whyte J., Bagiella E., et al. (2012). *Placebo-controlled trial of amantadine for severe traumatic brain injury*. *New England Journal of Medicine*, 366(9), 819–826.

¹⁹¹ Alexopoulos G.S., Katz I.R., Reynolds C.F. 3rd, Carpenter D., Docherty J.P., Ross R.W. (2001). *Pharmacotherapy of depression in older patients: a summary of the expert consensus guidelines*. *Journal of Psychiatric Practice*, 7(6), 361–376.

¹⁹² Arean P.A., Cook B.L. (2002). *Psychotherapy and combined psychotherapy/pharmacotherapy for late life depression*. *Biological Psychiatry*, 52(3), 293–303.

¹⁹³ Hollon S.D., Jarrett R.B., Nierenberg A.A., Thase M.E., Trivedi M., Rush A.J. (2005). *Psychotherapy and medication in the treatment of adult and geriatric depression: which monotherapy or combined treatment?* *Journal of Clinical Psychiatry*, 66(4), 455–468.

¹⁹⁴ Wagenaar D., Colenda C.C., Kreft M., Sawade J., Gardiner J., Poverrejan E. (2003). *Treating depression in nursing homes: practice guidelines in the real world*. *J Am Osteopath Assoc*. 103(10), 465–469.

¹⁹⁵ Crespy S.D., Van Haitsma K., Kleban M., Hann C.J. *Reducing Depressive Symptoms in Nursing Home Residents: Evaluation of the Pennsylvania Depression Collaborative Quality Improvement Program*. *J Healthc Qual*. 2016. Vol. 38, No. 6, pp. e76–e88.

process, and be useful during care transitions and when coordinating across providers. A full report of the comments is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Therefore, we are proposing to adopt the BIMS for use in the HH QRP. We are proposing to add the data elements that comprise the BIMS to the OASIS, and that HHAs would be required to report these data at SOC/ROC between January 1, 2019 and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019 through June 30, 2020 for the CY 2021 HH QRP. The BIMS data elements would be assessed at SOC/ROC only due to the relatively stable nature of the types of cognitive function assessed by the BIMS, making it unlikely that a patient's score on this assessment would change between the start and end of care. Assessment at discharge would introduce additional burden without improving the quality or usefulness of the data, and we believe it is unnecessary.

We are inviting public comment on these proposals.

ii. Confusion Assessment Method (CAM)

We are proposing that the data elements that comprise the Confusion Assessment Method (CAM) meet the definition of standardized patient assessment data for cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act. The CAM is a six-question instrument that screens for overall cognitive impairment, as well as distinguishes delirium or reversible confusion from other types of cognitive impairment. For more information on the CAM, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemakings*, available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html>.

The CAM was developed to identify the signs and symptoms of delirium. It results in a score that suggests whether the patient or resident should be assigned a diagnosis of delirium. Because patients and residents with multiple comorbidities receive services from PAC providers, it is important to assess delirium, as it is associated with

a high mortality rate and prolonged duration of stay in hospitalized older adults with dementia.¹⁹⁹ Assessing for signs and symptoms of delirium is clinically relevant for care planning by PAC providers.

The CAM is currently in use in two of the PAC assessments: The MDS 3.0 in SNFs and the LCDS in LTCHs. The CAM was tested in the PAC PRD where it was found to have substantial agreement for inter-rater reliability for the "Inattention and Disorganized Thinking" questions (kappa range of 0.70 to 0.73); and moderate agreement for the "Altered Level of Consciousness" question (kappa of 0.58).²⁰⁰

Clinical and subject matter expert advisors working with our data element contractor agreed that the CAM is feasible for use by PAC providers, that it assesses key aspects of cognition, and that this information about patient or resident cognition would be clinically useful both within and across PAC provider types. The CAM was also supported by a TEP that discussed and rated candidate data elements during a meeting on April 6 and 7, 2016. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data Technical Expert Panel Summary Report is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>. We requested public comment on the CAM from August 12 to September 12, 2016. Many commenters expressed support for use of the CAM, noting that it would provide important information for care planning and care coordination, and therefore, contribute to quality improvement. The commenters noted it is particularly helpful in distinguishing delirium and reversible confusion from other types of cognitive impairment. A full report of the comments is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Therefore, we are proposing to add the CAM data elements to the OASIS,

¹⁹⁹ Fick, D.M., Steis, M.R., Waller, J.L., & Inouye, S.K. (2013). "Delirium superimposed on dementia is associated with prolonged length of stay and poor outcomes in hospitalized older adults." *J of Hospital Med* 8(9): 500–505.

²⁰⁰ Gage B., Morley M., Smith L., et al. (2012). *Post-Acute Care Payment Reform Demonstration* (Final report, Volume 2 of 4). Research Triangle Park, NC: RTI International.

and that HHAs would be required to report these data for the CY 2020 HH QRP at SOC/ROC and discharge between January 1, 2019 and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019 through June 30, 2020 for the CY 2021 HH QRP.

We are inviting public comment on these proposals.

iii. Behavioral Signs and Symptoms

We are proposing that the Behavioral Signs and Symptoms data elements meet the definition of standardized patient assessment data for cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act. The proposed data elements consist of three Behavioral Signs and Symptoms questions and result in three scores that categorize patients as having or not having certain types of behavioral signs and symptoms. For more information on the Behavioral Signs and Symptoms data elements, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking*, available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html>.

The questions included in the Behavioral Signs and Symptoms group assess whether the patient or resident has exhibited any behavioral symptoms that may indicate cognitive impairment or other mental health issues during the assessment period, including physical, verbal, and other disruptive or dangerous behavioral symptoms, but excluding patient wandering. Such behaviors can indicate unrecognized needs and care preferences and are associated most commonly with dementia and other cognitive impairment, and less commonly with adverse drug events, mood disorders, and other conditions.²⁰¹ Assessing behavioral disturbances can lead to early intervention, patient- and resident-centered care planning, clinical decision support, and improved staff and patient or resident safety. Assessment and documentation of these behaviors can help inform care planning and patient transitions, and provide important information about resource use.

Data elements that capture behavioral symptoms are currently included in two

²⁰¹ Desai A, Grossbert G. Recognition and management of behavioral disturbances in dementia. *The Primary Care Companion to the Journal of Clinical Psychiatry*. 2001; 3(3):93–109.

of the PAC assessments: The MDS 3.0 in SNFs and the OASIS-C2 in HHAs. In the MDS, each question includes four response options ranging from “behavior not exhibited” (0) to behavior “occurred daily” (3). The OASIS-C2 includes some similar data elements which record the frequency of disruptive behaviors on a 6-point scale ranging from “never” (0) to “at least daily” (5). Data elements that mirror those used in the MDS and serve the same assessment purpose were tested in post-acute providers in the PAC PRD and found to be clinically relevant, meaningful for care planning, and feasible for use in each of the four PAC settings.²⁰²

The proposed data elements were supported by comments from the Standardized Patient Assessment Data TEP held by our data element contractor. The TEP identified patient and resident behaviors as an important consideration for resource intensity and care planning, and affirmed the importance of the standardized assessment of patient behaviors through data elements such as those in use in the MDS. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data Technical Expert Panel Summary Report is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Because the PAC PRD version of the Behavioral Signs and Symptoms data elements were previously tested across PAC providers, we solicited additional feedback on this version of the data elements by including these data elements in a call for public comment that was open from August 12 to September 12, 2016. Consistent with the TEP discussion on the importance of patient and resident behaviors, many commenters expressed support for use of the Behavioral Signs and Symptoms data elements, noting that they would provide useful information about patient and resident behavior at both admission and discharge, and contribute to care planning regarding the most appropriate treatment and resource use for the patient or resident. Public comment also supported the use of a highly similar MDS version of the data elements to provide continuity with existing assessment processes in SNFs.

²⁰² Gage B., Morley M., Smith L., et al. (2012). Post-Acute Care Payment Reform Demonstration (Final report, Volume 2 of 4). Research Triangle Park, NC: RTI International.

A full report of the comments is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Therefore, we are proposing the MDS version of the Behavioral Signs and Symptoms data elements because they focus more closely on behavioral symptoms than the OASIS data elements, and include more detailed response categories than those used in the PAC PRD version, capturing more information about the frequency of behaviors. We are proposing that HHAs would be required to report these data for the CY 2020 HH QRP at SOC/ROC and discharge between January 1, 2019 and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019 through June 30, 2020 for the CY 2021 HH QRP.

We are inviting public comment on these proposals.

iv. Patient Health Questionnaire-2 (PHQ-2)

We are proposing that the PHQ-2 data elements meet the definition of standardized patient assessment data for cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act. The proposed data elements consist of the PHQ-2 two-item questionnaire that assesses the cardinal criteria for depression: depressed mood and anhedonia (inability to feel pleasure). For more information on the PHQ-2, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking*, available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQQualityMeasures.html>.

Depression is a common mental health condition that is often missed and under-recognized. Assessing depression helps PAC providers better understand the needs of their patients and residents by: Prompting further evaluation (that is, to establish a diagnosis of depression); elucidating the patient's or resident's ability to participate in therapies for conditions other than depression during their stay; and identifying appropriate ongoing treatment and support needs at the time of discharge. A PHQ-2 score beyond a predetermined threshold signals the need for additional clinical assessment to determine a depression diagnosis.

The proposed data elements that comprise the PHQ-2 are currently used in the OASIS-C2 for HHAs and the MDS 3.0 for SNFs (as part of the PHQ-9). The PHQ-2 data elements were tested in the PAC PRD, where they were found to have almost perfect agreement for inter-rater reliability (kappa range of 0.84 to 0.91) when tested by all four PAC providers.²⁰³

Clinical and subject matter expert advisors working with our data element contractor agreed that the PHQ-2 is feasible for use in PAC, that it assesses key aspects of mental status, and that this information about patient or resident mood would be clinically useful both within and across PAC settings. We note that both the PHQ-9 and the PHQ-2 were supported by TEP members who discussed and rated candidate data elements during a meeting on April 6 and 7, 2016. They particularly noted that the brevity of the PHQ-2 made it feasible with low burden for both assessors and PAC patients or residents. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data Technical Expert Panel Summary Report is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

To solicit additional feedback on the PHQ-2, we requested public comment from August 12 to September 12, 2016. Many commenters provided feedback on using the PHQ-2 for the assessment of mood. Overall, commenters believed that collecting these data elements across PAC settings was appropriate, given the role that depression plays in well-being. Several commenters expressed support for an approach that would use PHQ-2 as a gateway to the longer PHQ-9 and would maintain the reduced burden on most patients and residents, as well as test administrators, which is a benefit of the PHQ-2, while ensuring that the PHQ-9, which exhibits higher specificity,²⁰⁴ would be administered for patients and residents who showed signs and symptoms of depression on the PHQ-2. Specific

²⁰³ Gage B., Smith L., Ross J. et al. (2012). The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set (Final Report on Reliability Testing, Volume 2 of 3). Research Triangle Park, NC: RTI International.

²⁰⁴ Arroll B, Goodyear-Smith F, Crengle S, Gunn J, Kerse N, Fishman T, et al. Validation of PHQ-2 and PHQ-9 to screen for major depression in the primary care population. *Annals of family medicine*. 2010;8(4):348–53. doi: 10.1370/afm.1139 pmid:20644190; PubMed Central PMCID: PMC2906530.

comments are described in a full report available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Therefore, we are proposing to adopt the PHQ-2 data elements for use in the HH QRP as standardized patient assessment data. As noted above in this section, the PHQ-2 is already included on the OASIS. HHAs would be required to report these data for the CY 2020 HH QRP at SOC/ROC and discharge between January 1, 2019 and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019 through June 30, 2020 for the CY 2021 HH QRP.

We are inviting public comment on these proposals.

c. Special Services, Treatments, and Interventions Data

Special services, treatments, and interventions performed in PAC can have a major effect on an individual's health status, self-image, and quality of life. The assessment of these special services, treatments, and interventions in PAC is important to ensure the continuing appropriateness of care for the patients and residents receiving them, and to support care transitions from one PAC setting to another, an acute care hospital, or discharge. Accurate assessment of special services, treatments, and interventions of patients and residents served by PAC providers are expected to have a positive impact on the National Quality Strategy's domains of patient and family engagement, patient safety, care coordination, clinical process/effectiveness, and efficient use of healthcare resources.

For example, standardized assessment of special services, treatments, and interventions used in PAC can promote patient and resident safety through appropriate care planning (for example, mitigating risks such as infection or pulmonary embolism associated with central intravenous access), and identifying life-sustaining treatments that must be continued, such as mechanical ventilation, dialysis, suctioning, and chemotherapy, at the time of discharge or transfer. Standardized assessment of these data elements will enable or support: Clinical decision-making and early clinical intervention; person-centered, high quality care through, for example, facilitating better care continuity and

coordination; better data exchange and interoperability between settings; and longitudinal outcome analysis. Hence, reliable data elements assessing special services, treatments, and interventions are needed to initiate a care plan that can improve, maintain, or best manage a patient or resident's condition and reduce the possibility of adverse events.

We are proposing 15 special services, treatments, and interventions as presented below in this section grouped by cancer treatments, respiratory treatments, other treatments, and nutritional approaches. A TEP convened by our data element contractor provided input on the 15 data elements for Special Services, Treatments, and Interventions. This TEP, held on January 5 and 6, 2017, opined that these data elements are appropriate for standardization because they would provide useful clinical information to inform care planning and care coordination. The TEP affirmed that assessment of these services and interventions is standard clinical practice, and that the collection of these data by means of a list and checkbox format would conform with common workflow for PAC providers. A full report of the TEP discussion is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

i. Cancer Treatment: Chemotherapy (IV, Oral, Other)

We are proposing that the Chemotherapy (IV, Oral, Other) data elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data elements consist of the principal Chemotherapy data element and three sub-elements: IV Chemotherapy, Oral Chemotherapy, and Other. For more information on the Chemotherapy (IV, Oral, Other) data elements, we refer readers to the document titled, <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html>.

Chemotherapy is a type of cancer treatment that uses drugs to destroy cancer cells. It is typically used when a patient has a malignancy (cancer), which is a serious, often life-threatening or life-limiting condition. Both intravenous (IV) and oral chemotherapy can have serious side effects, including nausea/vomiting, extreme fatigue, risk

of infection due to a suppressed immune system, anemia, and an increased risk of bleeding due to low platelet counts. Oral chemotherapy can have as many side effects as IV chemotherapy, but can also be significantly more convenient and less resource-intensive to administer. Because of the toxicity of these agents, special care must be exercised in handling and transporting chemotherapy drugs. IV chemotherapy may be given by peripheral IV, but is more commonly given via an indwelling central line, which raises the risk of bloodstream infections. Given the significant burden of malignancy, the resource intensity of administering chemotherapy, and the side effects and potential complications of these highly-toxic medications, assessing the receipt of chemotherapy is important in the PAC setting for care planning and determining resource use.

The need for chemotherapy predicts resource intensity, both because of the complexity of administering these potent, toxic drug combinations under specific protocols, and because of what the need for chemotherapy signals about the patient's underlying medical condition. Furthermore, the resource intensity of IV chemotherapy is higher than for oral chemotherapy, as the protocols for administration and the care of the central line (if present) require significant resources.

The Chemotherapy (IV, Oral, Other) data elements consist of a principal data element and three sub-elements: IV chemotherapy, which is generally resource-intensive; oral chemotherapy, which is less invasive and generally less intensive with regard to administration protocols; and a third category provided to enable the capture of other less common chemotherapeutic approaches. This third category is potentially associated with higher risks and is more resource intensive due to delivery by other routes (for example, intraventricular or intrathecal).

The principal Chemotherapy data element is currently in use in the MDS 3.0. One proposed sub-element, IV Chemotherapy, was tested in the PAC PRD and found feasible for use in each of the four PAC settings. We solicited public comment on IV Chemotherapy from August 12 to September 12, 2016. Several commenters provided support for the data element and suggested it be included as standardized patient assessment data. Commenters stated that assessing the use of chemotherapy services is relevant to share across the care continuum to facilitate care coordination and care transitions and noted the validity of the data element.

Commenters also noted the importance of capturing all types of chemotherapy, regardless of route, and stated that collecting data only on patients and residents who received chemotherapy by IV would limit the usefulness of this standardized data element. A full report of the comments is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Therefore, we are proposing that the Chemotherapy (IV, Oral, Other) data elements with a principal data element and three sub-elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the Chemotherapy (IV, Oral, Other) data elements to the OASIS, and that HHAs would be required to report these data for the CY 2020 HH QRP at SOC/ROC and discharge between January 1, 2019 and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019, through June 30, 2020 for the CY 2021 HH QRP.

We are inviting public comment on these proposals.

ii. Cancer Treatment: Radiation

We are proposing that the Radiation data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data element consists of the single Radiation data element. For more information on the Radiation data element, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking*, available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html>.

Radiation is a type of cancer treatment that uses high-energy radioactivity to stop cancer by damaging cancer cell DNA, but it can also damage normal cells. Radiation is an important therapy for particular types of cancer, and the resource utilization is high, with frequent radiation sessions required, often daily for a period of several weeks. Assessing whether a patient or resident is receiving radiation therapy is important to determine resource

utilization, as PAC patients and residents will need to be transported to and from radiation treatments, and monitored and treated for side effects after receiving this intervention. Therefore, assessing the receipt of radiation therapy, which would compete with other care processes given the time burden, would be important for care planning and care coordination by PAC providers.

The Radiation data element is currently in use in the MDS 3.0. This data element was not tested in the PAC PRD. However, public comment and other expert input on the Radiation data element supported its importance and clinical usefulness for patients in PAC settings, due to the side effects and consequences of radiation treatment on patients that need to be considered in care planning and care transitions. To solicit additional feedback on the Radiation data element we are proposing, we requested public comment from August 12 to September 12, 2016. Several commenters provided support for the data element, noting the relevance of this data element in facilitating care coordination and supporting care transitions, the feasibility of the item, and the potential for quality improvement. A full report of the comments is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

The proposed data element was presented to and supported by the TEP held by our data element contractor on January 5 and 6, 2017, which opined that Radiation provided important corollary information about cancer treatment in addition to Chemotherapy (IV, Oral, Other), and that, because capturing this information is a customary part of clinical practice, the proposed data element would be feasible, reliable, and easily incorporated into existing workflow.

Therefore, we are proposing that the Radiation data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the Radiation data element to the OASIS, and that HHAs would be required to report these data for the CY 2020 HH QRP at SOC/ROC and discharge between January 1, 2019 and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning

with July 1, 2019 through June 30, 2020 for the CY 2021 HH QRP.

We are inviting public comment on these proposals.

iii. Respiratory Treatment: Oxygen Therapy (Continuous, Intermittent)

We are proposing that the Oxygen Therapy (Continuous, Intermittent) data elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data elements consist of the principal Oxygen data element and two sub-elements, "Continuous" (whether the oxygen was delivered continuously, typically defined as ≥ 14 hours per day), or "Intermittent." For more information on the Oxygen Therapy (Continuous, Intermittent) data elements, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking*, available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html>.

Oxygen therapy provides a patient or resident with extra oxygen when medical conditions such as chronic obstructive pulmonary disease, pneumonia, or severe asthma prevent the patient or resident from getting enough oxygen from room air. Oxygen administration is a resource-intensive intervention, as it requires specialized equipment such as the source of oxygen, delivery systems (for example, oxygen concentrator, liquid oxygen containers, and high-pressure systems), the patient interface (for example, nasal cannula or mask), and other accessories (for example, regulators, filters, tubing). These data elements capture patient or resident use of two types of oxygen therapy (continuous and intermittent) which are reflective of intensity of care needs, including the level of monitoring and direct patient care required. Assessing the receipt of this service is important for care planning and resource use for PAC providers.

The proposed data elements were developed based on similar data elements that assess oxygen therapy, currently in use in the MDS 3.0 ("Oxygen Therapy") and OASIS-C2 ("Oxygen (intermittent or continuous)"), and a data element tested in the PAC PRD that focused on intensive oxygen therapy ("High O2 Concentration Delivery System with FiO2 $> 40\%$ ").

As a result of input from expert advisors, we solicited public comment on the single data element, Oxygen

(inclusive of intermittent and continuous oxygen use), from August 12 to September 12, 2016. Several commenters supported the importance of the Oxygen data element, noting feasibility of this item in PAC, and the relevance in facilitating care coordination and supporting care transitions, but suggesting that the extent of oxygen use be documented. A full report of the comments is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

As a result of public comment and input from expert advisors about the importance and clinical usefulness of documenting the extent of oxygen use, we expanded the single data element to include two sub-elements, intermittent and continuous.

Therefore, we are proposing that the Oxygen Therapy (Continuous, Intermittent) data elements with a principal data element and two sub-elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to expand the existing Oxygen (intermittent or continuous)-data element in the OASIS to include sub-elements for Continuous and Intermittent, and that HHAs would be required to report these data for the CY 2020 HH QRP at SOC/ROC and discharge between January 1, 2019 and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019 through June 30, 2020 for the CY 2021 HH QRP.

We are inviting public comment on these proposals.

iv. Respiratory Treatment: Suctioning (Scheduled, As needed)

We are proposing that the Suctioning (Scheduled, As needed) data elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data elements consist of the principal Suctioning data element, and two sub-elements, “Scheduled” and “As needed.” These sub-elements capture two types of suctioning. “Scheduled” indicates suctioning based on a specific frequency, such as every hour. “As needed” means suctioning only when indicated. For more information on the

Suctioning (Scheduled, As needed) data elements, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking*, available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html>.

Suctioning is an intervention used to clear secretions from the airway when a person cannot clear those secretions on his or her own. It is done by aspirating secretions through a catheter connected to a suction source. Types of suctioning include oropharyngeal and nasopharyngeal suctioning, nasotracheal suctioning, and suctioning through an artificial airway such as a tracheostomy tube. Oropharyngeal and nasopharyngeal suctioning are a key part of many patients’ care plans, both to prevent the accumulation of secretions that can lead to aspiration pneumonia (a common condition in patients with inadequate gag reflexes), and to relieve obstructions from mucus plugging during an acute or chronic respiratory infection, which can often lead to desaturation and increased respiratory effort. Suctioning can be done on a scheduled basis if the patient is judged to clinically benefit from regular interventions; or can be done as needed, such as when secretions become so copious that gurgling or choking is noted, or a sudden desaturation occurs from a mucus plug. As suctioning is generally performed by a care provider rather than independently, this intervention can be quite resource-intensive if it occurs every hour, for example, rather than once a shift. It also signifies an underlying medical condition that prevents the patient from clearing his/her secretions effectively (such as after a stroke, or during an acute respiratory infection). Generally, suctioning is necessary to ensure that the airway is clear of secretions which, if left, can inhibit successful oxygenation of the individual and/or lead to infection. The intent of suctioning is to maintain a patent airway, the loss of which can lead to death, or complications associated with hypoxia.

The proposed data elements are based on an item currently in use in the MDS 3.0 (“Suctioning” without the two sub-elements), and data elements tested in the PAC PRD that focused on the frequency of suctioning required for patients with tracheostomies (“Trach Tube with Suctioning: Specify most intensive frequency of suctioning during stay [Every ____ hours]”).

Clinical and subject matter expert advisors working with our data element contractor agreed that the proposed Suctioning (Scheduled, As needed) data elements are feasible for use in PAC, and that they indicate important treatment that would be clinically useful to capture both within and across PAC providers. We solicited public comment on the suctioning data element currently included in the MDS 3.0 from August 12 to September 12, 2016. Several commenters wrote in support of this data element, noting feasibility of this item in PAC, and the relevance of this data element to facilitating care coordination and supporting care transitions. We also received comments suggesting that we examine the frequency of suctioning to better understand the use of staff time, the impact on a patient or resident’s capacity to speak and swallow, and intensity of care required. Based on these comments, we decided to add two sub-elements (scheduled and as needed) to the suctioning element. The proposed data elements, Suctioning (Scheduled, As needed) includes both the principal suctioning data element that is included on the MDS 3.0 and two sub-elements, “scheduled” and “as needed.” A full report of the comments is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

A TEP convened by the data element contractor provided input on the proposed data elements. This TEP, held on January 5 and 6, 2017, opined that these data elements are appropriate for standardization because they would provide useful clinical information to inform care planning and care coordination. The TEP affirmed that assessment of these services and interventions is standard clinical practice. A full report of the TEP discussion is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Therefore, we are proposing that the Suctioning (Scheduled, As needed) data elements with a principal data element and two sub-elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the Suctioning (Scheduled, As needed) data elements to the OASIS, and that HHAs would be

required to report these data for the CY 2020 HH QRP at SOC/ROC and discharge between January 1, 2019, and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019, through June 30, 2020 for the CY 2021 HH QRP.

We are inviting public comment on these proposals.

v. Respiratory Treatment: Tracheostomy Care

We are proposing that the Tracheostomy Care data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data element consists of the single Tracheostomy Care data element. For more information on the Tracheostomy Care data element, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking*, available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html>.

A tracheostomy provides an airway to help a patient or resident breathe when the usual route for breathing is obstructed or impaired. Generally, in all of these cases, suctioning is necessary to ensure that the tracheostomy tube is clear of secretions which can inhibit successful oxygenation of the individual, or accumulate and cause infection. Often, individuals with tracheostomies are also receiving supplemental oxygenation. The presence of a tracheostomy, whether permanent or temporary, warrants careful monitoring and immediate intervention if the tracheostomy tube becomes occluded or dislodged. While in rare cases the presence of a tracheostomy is not associated with increased care demands (and in some of those instances, the care of the ostomy is performed by the patient), in general the presence of such a device is associated with increased patient risk and resource use. Tracheostomy care should include close monitoring to prevent occlusion or decannulation, skin infection or necrosis, and other complications to ensure adequate air flow and oxygenation. In addition to suctioning, skin care, dressing changes, and replacement or cleaning of the tracheostomy cannula (tube), is also a critical part of the tracheostomy care plan. Regular cleaning and suctioning is

important in preventing infections such as pneumonia, preventing skin breakdown, and preventing any occlusions leading to inadequate oxygenation.

The proposed data element is currently in use in the MDS 3.0 ("Tracheostomy care"). Data elements ("Trach Tube with Suctioning") that were tested in the PAC PRD included an equivalent principal data element on the presence of a tracheostomy. This data element was found feasible for use in each of the four PAC settings as the data collection aligned with usual work flow.

Clinical and subject matter expert advisors working with our data element contractor agreed that the Tracheostomy Care data element is feasible for use in PAC and that it assesses an important treatment that would be clinically useful both within and across PAC provider types.

We solicited public comment on this data element from August 12 to September 12, 2016. Several commenters wrote in support of this data element, noting the feasibility of this item in PAC, and the relevance of this data element to facilitating care coordination and supporting care transitions. A full report of the comments is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

A TEP convened by the data element contractor provided input on the proposed data elements. This TEP, held on January 5 and 6, 2017, opined that these data elements are appropriate for standardization because they would provide useful clinical information to inform care planning and care coordination. The TEP affirmed that assessment of these services and interventions is standard clinical practice. A full report of the TEP discussion is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Therefore, we are proposing that the Tracheostomy Care data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the Tracheostomy Care data element to the OASIS, and that HHAs would be required to report these data for the CY 2020 HH QRP at SOC/ROC and

discharge between January 1, 2019 and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019, through June 30, 2020 for the CY 2021 HH QRP.

We are inviting public comment on these proposals.

vi. Respiratory Treatment: Non-Invasive Mechanical Ventilator (BiPAP, CPAP)

We are proposing that the Non-invasive Mechanical Ventilator (Bilevel Positive Airway Pressure [BiPAP], Continuous Positive Airway Pressure [CPAP]) data elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data elements consist of the principal Non-invasive Mechanical Ventilator data element and two sub-elements, BiPAP and CPAP. For more information on the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data elements, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking*, available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html>.

BiPAP and CPAP are respiratory support devices that prevent the airways from closing by delivering slightly pressurized air via electronic cycling throughout the breathing cycle (Bilevel Positive Airway Pressure, referred to as BiPAP) or through a mask continuously (Continuous PAP, referred to as CPAP). Assessment of non-invasive mechanical ventilation is important in care planning, as both CPAP and BiPAP are resource-intensive (although less so than invasive mechanical ventilation) and signify a more complex or underlying medical condition. Particularly when used in the context of acute illness or progressive respiratory decline, additional staff (for example, respiratory therapists) are required to monitor and adjust the CPAP and BiPAP settings. Additionally the patient or resident may require more nursing assessment, education, and interventions, such as pulse oximetry or venipuncture for blood gas evaluation.

Data elements that assess BiPAP and CPAP are currently included on the OASIS-C2 for HHAs ("Continuous/Bilevel positive airway pressure"), LCDS for the LTCH setting ("Non-invasive Ventilator (BiPAP, CPAP)"), and the MDS 3.0 for the SNF setting ("BiPAP/

CPAP”). A data element that focused on CPAP was tested across the four PAC providers in the PAC PRD study and found to be feasible for standardization. All of these data elements assess BiPAP or CPAP with a single check box, not separately.

Clinical and subject matter expert advisors working with our data element contractor agreed that the standardized assessment of Non-invasive Mechanical Ventilator (BiPAP, CPAP) data elements would be feasible for use in PAC, and assess an important treatment that would be clinically useful both within and across PAC provider types.

To solicit additional feedback on the form of the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data elements best suited for standardization, we requested public comment on a single data element, BiPAP/CPAP, equivalent (but for labeling) to what is currently in use on the MDS, OASIS, and LCDs, from August 12 to September 12, 2016. Several commenters wrote in support of this data element, noting the feasibility of these items in PAC, and the relevance of these data elements for facilitating care coordination and supporting care transitions. In addition, there was support in the public comment responses for separating out BiPAP and CPAP as distinct sub-elements, as they are therapies used for different types of patients and residents. A full report of the comments is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

A TEP convened by the data element contractor provided input on the proposed data elements. This TEP, held on January 5 and 6, 2017, opined that these data elements are appropriate for standardization because they would provide useful clinical information to inform care planning and care coordination. The TEP affirmed that assessment of these services and interventions is standard clinical practice. A full report of the TEP discussion is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Therefore, we are proposing that the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data elements with a principal data element and two sub-elements meet the definition of standardized patient assessment data for special services, treatments, and

interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing that the existing “Continuous/Bi-level positive airway pressure” data element in the OASIS be expanded and relabeled as the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data elements, and that HHAs would be required to report these data for the CY 2020 HH QRP at SOC/ROC and discharge between January 1, 2019 and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019, through June 30, 2020 for the CY 2021 HH QRP.

We are inviting public comment on these proposals.

vii. Respiratory Treatment: Invasive Mechanical Ventilator

We are proposing that the Invasive Mechanical Ventilator data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data element consists of a single Invasive Mechanical Ventilator data element. For more information on the Invasive Mechanical Ventilator data element, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking*, available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html>.

Invasive mechanical ventilation includes ventilators and respirators that ventilate the patient through a tube that extends via the oral airway into the pulmonary region (intubation), or through a surgical opening directly into the trachea (tracheostomy). Thus, assessment of invasive mechanical ventilation is important in care planning and risk mitigation. Ventilation in this manner is a resource-intensive therapy associated with life-threatening conditions without which the patient or resident would not survive. However, ventilator use has inherent risks requiring close monitoring. Failure to adequately care for the patient or resident who is ventilator dependent can lead to iatrogenic events such as death, pneumonia and sepsis. Mechanical ventilation further signifies the complexity of the patient’s underlying medical or surgical condition. Of note, invasive mechanical

ventilation is associated with high daily and aggregate costs.²⁰⁵

Data elements that capture invasive mechanical ventilation, but vary in their level of specificity, are currently in use in the MDS 3.0 (“Ventilator or respirator”), LCDs (“Invasive Mechanical Ventilator: weaning” and “Invasive Mechanical Ventilator: non-weaning”), and related data elements that assess invasive ventilator use and weaning status were tested in the PAC PRD (“Ventilator—Weaning” and “Ventilator—Non-Weaning”) and found feasible for use in each of the four PAC settings.

Clinical and subject matter expert advisors working with our data element contractor agreed that assessing Invasive Mechanical Ventilator use is feasible in PAC, and would be clinically useful both within and across PAC providers.

To solicit additional feedback on the form of a data element on this topic that would be appropriate for standardization, data elements that assess invasive ventilator use and weaning status that were tested in the PAC PRD (“Ventilator—Weaning” and “Ventilator—Non-Weaning”) were included in a call for public comment that was open from August 12 to September 12, 2016 because they were being considered for standardization. Several commenters wrote in support of these data elements, highlighting the importance of this information in supporting care coordination and care transitions. Some commenters expressed concern about the appropriateness for standardization, given the prevalence of ventilator weaning across PAC providers; the timing of administration; how weaning is defined; and how weaning status in particular relates to quality of care. These comments guided the decision to propose a single data element focused on current use of invasive mechanical ventilation only, and does not attempt to capture weaning status. A full report of the comments is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

A TEP convened by the data element contractor provided input on the proposed data elements. This TEP, held on January 5 and 6, 2017, opined that these data elements are appropriate for standardization because they would

²⁰⁵ Wunsch, H., Linde-Zwirble, W.T., Angus, D. C., Hartman, M.E., Milbrandt, E.B., & Kahn, J.M. (2010). “The epidemiology of mechanical ventilation use in the United States.” *Critical Care Med* 38(10): 1947–1953.

provide useful clinical information to inform care planning and care coordination. The TEP affirmed that assessment of these services and interventions is standard clinical practice. A full report of the TEP discussion is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Therefore, we are proposing that the Invasive Mechanical Ventilator data element that assesses the use of an invasive mechanical ventilator, but does not assess weaning status, meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the Invasive Mechanical Ventilator data element to the OASIS, and that HHAs would be required to report these data for the CY 2020 HH QRP at SOC/ROC and discharge between January 1, 2019 and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019 through June 30, 2020 for the CY 2021 HH QRP.

We are inviting public comment on these proposals.

viii. Other Treatment: Intravenous (IV) Medications (Antibiotics, Anticoagulation, Other)

We are proposing that the IV Medications (Antibiotics, Anticoagulation, Other) data elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data elements consist of the principal IV Medications data element and three sub-elements, Antibiotics, Anticoagulation, and Other. For more information on the IV Medications (Antibiotics, Anticoagulation, Other) data elements, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking*, available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQQualityMeasures.html>.

IV medications are solutions of a specific medication (for example, antibiotics, anticoagulants) administered directly into the venous circulation via a port or intravenous

tubing. IV medications are administered via intravenous push (bolus), single, intermittent, or continuous infusion through a catheter placed into the vein (for example, through central, midline, or peripheral ports). Further, IV medications are more resource intensive to administer than oral medications, and signify a higher patient complexity (and often higher severity of illness).

The clinical indications for each of the sub-elements of the IV Medication data element (Antibiotics, Anticoagulants, and Other) are very different. IV antibiotics are used for severe infections when: (1) The bioavailability of the oral form of the medication would be inadequate to kill the pathogen; (2) an oral form of the medication does not exist; or (3) the patient is unable to take the medication by mouth. IV anticoagulants refer to anti-clotting medications (that is, “blood thinners”), often used for the prevention and treatment of deep vein thrombosis and other thromboembolic complications. IV anticoagulants are commonly used in patients with limited mobility (either chronically or acutely, in the post-operative setting), who are at risk of deep vein thrombosis, or patients with certain cardiac arrhythmias such as atrial fibrillation. The indications, risks, and benefits of each of these classes of IV medications are distinct, making it important to assess and monitor each separately in PAC. Knowing whether or not patients are receiving IV medication and the type of medication provided by each PAC provider will improve quality of care.

The principal IV Medication data element is currently in use on the MDS 3.0 and there is a related data element in OASIS–C2 that collects information on Intravenous and Infusion Therapies. One sub-element of the proposed data elements, IV Anti-coagulants, and two other data elements related to IV therapy (IV Vasoactive Medications and IV Chemotherapy), were tested in the PAC PRD and found feasible for use in that the data collection aligned with usual work flow in each of the four PAC settings, demonstrating the feasibility of collecting IV medication information, including type of IV medication, through similar data elements in these settings.

Clinical and subject matter expert advisors working with our data element contractor agreed that standardized collection of information on medications, including IV medications, would be feasible in PAC, and assess an important treatment that would be clinically useful both within and across PAC provider types.

We solicited public comment on a related data element, Vasoactive Medications, from August 12 to September 12, 2016. While commenters supported this data element with one noting the importance of this data element in supporting care transitions, others criticized the need for collecting specifically on Vasoactive Medications, giving feedback that the data element was too narrowly focused. Additionally, comments received indicated that the clinical significance of vasoactive medications administration alone was not high enough in PAC to merit mandated assessment, noting that related and more useful information could be captured in an item that assessed all IV medication use.

Overall, public comment indicated the importance of including the additional check box data elements to distinguish particular classes of medications. A full report of the comments is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

A TEP convened by the data element contractor provided input on the proposed data elements. This TEP, held on January 5 and 6, 2017, opined that these data elements are appropriate for standardization because they would provide useful clinical information to inform care planning and care coordination. The TEP affirmed that assessment of these services and interventions is standard clinical practice. A full report of the TEP discussion is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Therefore, we are proposing that the IV Medications (Antibiotics, Anticoagulation, Other) data elements with a principal data element and three sub-elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the IV Medications (Antibiotics, Anticoagulation, Other) data elements to the OASIS, and that HHAs would be required to report these data for the CY 2020 HH QRP at SOC/ROC and discharge between January 1, 2019 and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12

months of such data reporting beginning with July 1, 2019 through June 30, 2020 for the CY 2021 HH QRP.

We are inviting public comment on these proposals.

ix. Other Treatment: Transfusions

We are proposing that the Transfusions data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data element consists of the single Transfusions data element. For more information on the Transfusions data element, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking*, available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQQualityMeasures.html>.

Transfusion refers to introducing blood, blood products, or other fluid into the circulatory system of a person. Blood transfusions are based on specific protocols, with multiple safety checks and monitoring required before, during, and after the infusion to prevent errors and adverse events. Coordination with the provider's blood bank is necessary, as well as documentation by clinical staff to ensure compliance with regulatory requirements. In addition, the need for transfusions signifies underlying patient complexity that is likely to require care coordination and patient monitoring, and impacts planning for transitions of care, as transfusions are not performed by all PAC providers.

The proposed data element was selected from three existing assessment items on transfusions and related services, currently in use in the MDS 3.0 ("Transfusions") and OASIS-C2 ("Intravenous or Infusion Therapy"), and a data element tested in the PAC PRD ("Blood Transfusions"), that was found feasible for use in each of the four PAC settings. We chose to propose the MDS version because of its greater level of specificity over the OASIS-C2 data element. This selection was informed by expert advisors and reviewed and supported in the proposed form by the Standardized Patient Assessment Data TEP held by our data element contractor on January 5 and 6, 2017. A full report of the TEP discussion is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/>

IMPACT-Act-Downloads-and-Videos.html.

Therefore, we are proposing that the Transfusions data element that is currently in use in the MDS meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the Transfusions data element to the OASIS, and that HHAs would be required to report these data for the CY 2020 HH QRP at SOC/ROC and discharge between January 1, 2019 and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019 through June 30, 2020 for the CY 2021 HH QRP.

We are inviting public comment on these proposals.

x. Other Treatment: Dialysis (Hemodialysis, Peritoneal Dialysis)

We are proposing that the Dialysis (Hemodialysis, Peritoneal dialysis) data elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data elements consist of the principal Dialysis data element and two sub-elements, Hemodialysis and Peritoneal dialysis. For more information on the Dialysis (Hemodialysis, Peritoneal dialysis) data elements, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking*, available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQQualityMeasures.html>.

Dialysis is a treatment primarily used to provide replacement for lost kidney function. Both forms of dialysis (hemodialysis and peritoneal dialysis) are resource intensive, not only during the actual dialysis process but before, during, and after treatment. Patients and residents who need and undergo dialysis procedures are at high risk for physiologic and hemodynamic instability from fluid shifts and electrolyte disturbances, as well as infections that can lead to sepsis. Further, patients or residents receiving hemodialysis are often transported to a different facility, or at a minimum, to a different location in the same facility. Close monitoring for fluid shifts, blood pressure abnormalities, and other adverse effects is required prior to,

during and following each dialysis session. Nursing staff typically perform peritoneal dialysis at the bedside, and as with hemodialysis, close monitoring is required.

The principal Dialysis data element is currently included on the MDS 3.0 and the LCDS v3.0 and assesses the overall use of dialysis. The sub-elements for Hemodialysis and Peritoneal dialysis were tested across the four PAC providers in the PAC PRD study, and found to be feasible for standardization. Clinical and subject matter expert advisors working with our data element contractor opined that the standardized assessment of dialysis is feasible in PAC, and that it assesses an important treatment that would be clinically useful both within and across PAC providers. As the result of expert and public feedback, described below, we decided to propose data elements that include both the principal Dialysis data element and the two sub-elements (hemodialysis and peritoneal dialysis).

The Hemodialysis data element, which was tested in the PAC PRD, was included in a call for public comment that was open from August 12 to September 12, 2016. Commenters supported the assessment of hemodialysis and recommended that the data element be expanded to include peritoneal dialysis. Several commenters supported the Hemodialysis data element, noting the relevance of this information for sharing across the care continuum to facilitate care coordination and care transitions, the potential for this data element to be used to improve quality, and the feasibility for use in PAC. In addition, we received comment that the item would be useful in improving patient and resident transitions of care. Several commenters also stated that peritoneal dialysis should be included in a standardized data element on dialysis and recommended collecting information on peritoneal dialysis in addition to hemodialysis. The rationale for including peritoneal dialysis from commenters included the fact that patients and residents receiving peritoneal dialysis will have different needs at post-acute discharge compared to those receiving hemodialysis or not having any dialysis. Based on these comments, the Hemodialysis data element was expanded to include a principal Dialysis data element and two sub-elements, hemodialysis and peritoneal dialysis; these are the same two data elements that were tested in the PAC PRD. This expanded version, Dialysis (Hemodialysis, Peritoneal dialysis), are the data elements being proposed. A full report of the comments

is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We note that the Dialysis (Hemodialysis, Peritoneal dialysis) data elements were also supported by the TEP that discussed candidate data elements for Special Services, Treatments, and Interventions during a meeting on January 5 and 6, 2017. A full report of the TEP discussion is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Therefore, we are proposing that the Dialysis (Hemodialysis, Peritoneal dialysis) data elements with a principal data element and two sub-elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the Dialysis (Hemodialysis, Peritoneal dialysis) data elements to the OASIS, and that HHAs would be required to report these data for the CY 2020 HH QRP at SOC/ROC and discharge between January 1, 2019 and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019 through June 30, 2020 for the CY 2021 HH QRP.

We are inviting public comment on these proposals.

xi. Other Treatment: Intravenous (IV) Access (Peripheral IV, Midline, Central Line, Other)

We are proposing that the IV Access (Peripheral IV, Midline, Central line, Other) data elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data elements consist of the principal IV Access data element and four sub-elements, Peripheral IV, Midline, Central line, and Other. For more information on the IV Access (Peripheral IV, Midline, Central line, Other) data elements, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking*, available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html>.

Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.

Patients or residents with central lines, including those peripherally inserted or who have subcutaneous central line “port” access, always require vigilant nursing care to ensure patency of the lines and prevent any potentially life-threatening events such as infection, air embolism, or bleeding from an open lumen. Clinically complex patients and residents are likely to be receiving medications or nutrition intravenously. The sub-elements included in the IV Access data elements distinguish between peripheral access and different types of central access. The rationale for distinguishing between a peripheral IV and central IV access is that central lines confer higher risks associated with life-threatening events such as pulmonary embolism, infection, and bleeding.

The proposed IV Access (Peripheral IV, Midline, Central line, Other) data elements are not currently included on any of the mandated PAC assessment instruments. However, related data elements (for example, IV Medication in MDS 3.0 for SNF, Intravenous or infusion therapy in OASIS—C2 for HHAs) currently assess types of IV infusions or service. Several related data elements that describe types of IV infusions and services (for example, Central Line Management, IV Vasoactive Medications) were tested across the four PAC providers in the PAC PRD study, and found to be feasible for standardization.

Clinical and subject matter expert advisors working with our data element contractor agreed that assessing type of IV access would be feasible for use in PAC and that it assesses an important treatment that would be clinically useful both within and across PAC provider types.

We requested public comment on one of the PAC PRD data elements, Central Line Management, from August 12 to September 12, 2016. A central line is one type of IV access. Commenters supported the assessment of central line management and recommended that the data element be broadened to also include other types of IV access. Several commenters supported the data element, noting feasibility and importance for facilitating care coordination and care transitions. However, a few commenters recommended that the definition of this data element be broadened to include peripherally inserted central catheters (“PICC lines”) and midline IVs. Based on public comment feedback and in consultation with clinical and subject matter experts, we expanded the Central

Line Management data element to include more types of IV access (Peripheral IV, Midline, Central line, Other). This expanded version, IV Access (Peripheral IV, Midline, Central line, Other), are the data elements being proposed. A full report of the comments is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We note that the IV Access (Peripheral IV, Midline, Central line, Other) data elements were supported by the TEP that discussed candidate data elements for Special Services, Treatments, and Interventions during a meeting on January 5 and 6, 2017. A full report of the TEP discussion is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Therefore, we are proposing that the IV access (Peripheral IV, Midline, Central line, Other) data elements with a principal data element and four sub-elements meet the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the IV Access (Peripheral IV, Midline, Central line, Other) data elements to the OASIS and that HHAs would be required to report these data for the CY 2020 HH QRP at SOC/ROC and discharge between January 1, 2019 and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019 through June 30, 2020 for the CY 2021 HH QRP.

We are inviting public comment on these proposals.

xii. Nutritional Approach: Parenteral/IV Feeding

We are proposing that the Parenteral/IV Feeding data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data element consists of the single Parenteral/IV Feeding data element. For more information on the Parenteral/IV Feeding data element, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed*

Rulemaking, available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html>.

Parenteral/IV Feeding refers to a patient or resident being fed intravenously using an infusion pump, bypassing the usual process of eating and digestion. The need for IV/parenteral feeding indicates a clinical complexity that prevents the patient or resident from meeting his/her nutritional needs enterally, and is more resource intensive than other forms of nutrition, as it often requires monitoring of blood chemistries, and maintenance of a central line. Therefore, assessing a patient or resident's need for parenteral feeding is important for care planning and resource use. In addition to the risks associated with central and peripheral intravenous access, total parenteral nutrition is associated with significant risks such as embolism, sepsis, and glucose abnormalities.

The Parenteral/IV Feeding data element is currently in use in the MDS 3.0, and equivalent or related data elements are in use in the LCDs, IRF-PAI, and the OASIS-C2. An equivalent data element was tested in the PAC PRD ("Total Parenteral Nutrition") and found feasible for use in each of the four PAC settings, demonstrating the feasibility of collecting information about this nutritional service in these settings.

Total Parenteral Nutrition (an item with the same meaning as the proposed data element, but with the label used in the PAC PRD) was included in a call for public comment that was open from August 12 to September 12, 2016. Several commenters supported this data element, noting its relevance to facilitating care coordination and supporting care transitions. After the public comment period, the Total Parenteral Nutrition data element was re-named Parenteral/IV Feeding, to be consistent with how this data element is referred to in the MDS. A full report of the comments is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

A TEP convened by the data element contractor provided input on the proposed data elements. This TEP, held on January 5 and 6, 2017, opined that these data elements are appropriate for standardization because they would provide useful clinical information to inform care planning and care coordination. The TEP affirmed that assessment of these services and

interventions is standard clinical practice. A full report of the TEP discussion is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Therefore, we are proposing that the Parenteral/IV Feeding data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to rename the existing "Parenteral nutrition (TPN or lipids)" data element in the OASIS to the Parenteral/IV Feeding data element, and that HHAs would be required to report these data for the CY 2020 HH QRP at SOC/ROC and discharge between January 1, 2019, and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019, through June 30, 2020 for the CY 2021 HH QRP.

We are inviting public comment on these proposals.

xiv. Nutritional Approach: Feeding Tube

We are proposing that the Feeding Tube data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data element consists of the single Feeding Tube data element. For more information on the Feeding Tube data element, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking*, available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html>.

The majority of patients admitted to acute care hospitals experience deterioration of their nutritional status during their hospital stay, making assessment of nutritional status and method of feeding, if unable to eat orally, very important in PAC. A feeding tube can be inserted through the nose or the skin on the abdomen to deliver liquid nutrition into the stomach or small intestine. Feeding tubes are resource intensive and are therefore important to assess for care planning and resource use. Patients with severe malnutrition are at higher risk for a

variety of complications.²⁰⁶ In PAC settings, there are a variety of reasons that patients and residents may not be able to eat orally (including clinical or cognitive status).

The Feeding Tube data element is currently included in the MDS 3.0 for SNFs, and in the OASIS-C2 for HHAs, where it is labeled Enteral Nutrition. A related data element is collected in the IRF-PAI for IRFs (Tube/Parenteral Feeding). The testing of similar nutrition-focused data elements in the PAC PRD, and the current assessment of feeding tubes and related nutritional services and devices, demonstrates the feasibility of collecting information about this nutritional service in these settings.

Clinical and subject matter expert advisors working with our data element contractor opined that the Feeding Tube data element is feasible for use in PAC, and supported its importance and clinical usefulness for patients in PAC settings, due to the increased level of nursing care and patient monitoring required for patients who received enteral nutrition with this device.

We solicited additional feedback on an Enteral Nutrition data element (an item with the same meaning as the proposed data element, but with the label used in the OASIS) in a call for public comment that was open from August 12 to September 12, 2016. Several commenters supported the data element, noting the importance of assessing enteral nutrition status for facilitating care coordination and care transitions. After the public comment period, the Enteral Nutrition data element used in public comment was re-named Feeding Tube, indicating the presence of an assistive device. A full report of the comments is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We note that the Feeding Tube data element was also supported by the TEP that discussed candidate data elements for Special Services, Treatments, and Interventions during a meeting on January 5 and 6, 2017. A full report of the TEP discussion is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/>

²⁰⁶ Dempsey, D.T., Mullen, J.L., & Buzby, G.P. (1988). "The link between nutritional status and clinical outcome: can nutritional intervention modify it?" *Am J of Clinical Nutrition* 47(2): 352-356.

IMPACT-Act-Downloads-and-Videos.html.

Therefore, we are proposing that the Feeding Tube data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to rename the existing “Enteral nutrition (nasogastric, gastrostomy, jejunostomy, or any other artificial entry into the alimentary canal)” data element in the OASIS to the Feeding Tube data element and that HHAs would be required to report these data for the CY 2020 HH QRP at SOC/ROC and discharge between January 1, 2019, and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019 through June 30, 2020 for the CY 2021 HH QRP.

We are inviting public comment on these proposals.

xv. Nutritional Approach: Mechanically Altered Diet

We are proposing that the Mechanically Altered Diet data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data element consists of the single Mechanically Altered Diet data element. For more information on the Mechanically Altered Diet data element, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking*, available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html>.

The Mechanically Altered Diet data element refers to food that has been altered to make it easier for the patient or resident to chew and swallow, and this type of diet is used for patients and residents who have difficulty performing these functions. Patients with severe malnutrition are at higher risk for a variety of complications.²⁰⁷ In PAC settings, there are a variety of reasons that patients and residents may have impairments related to oral feedings, including clinical or cognitive status. The provision of a mechanically altered diet may be resource intensive, and can signal difficulties associated

with swallowing/eating safety, including dysphagia. In other cases, it signifies the type of altered food source, such as ground or puree, which will enable the safe and thorough ingestion of nutritional substances and ensure safe and adequate delivery of nourishment to the patient. Often, patients on mechanically altered diets also require additional nursing supports such as individual feeding, or direct observation, to ensure the safe consumption of the food product. Assessing whether a patient or resident requires a mechanically altered diet is therefore important for care planning and resource identification.

The proposed data element for a mechanically altered diet is currently included on the MDS 3.0 for SNFs. A related data element for modified food consistency/supervision is currently included on the IRF-PAI for IRFs. A related data element is included in the OASIS-C2 for HHAs that collects information about independent eating that requires “a liquid, pureed or ground meat diet.” The testing of similar nutrition-focused data elements in the PAC PRD, and the current assessment of various nutritional services across the four PAC settings, demonstrates the feasibility of collecting information about this nutritional service in these settings.

Clinical and subject matter expert advisors working with our data element contractor agreed that the proposed Mechanically Altered Diet data element is feasible for use in PAC, and it assesses an important treatment that would be clinically useful both within and across PAC settings. Expert input on the Mechanically Altered Diet data element highlighted its importance and clinical usefulness for patients in PAC settings, due to the increased monitoring and resource use required for patients on special diets. We note that the Mechanically Altered Diet data element was also supported by the TEP that discussed candidate data elements for Special Services, Treatments, and Interventions during a meeting on January 5 and 6, 2017. A full report of the TEP discussion is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Therefore, we are proposing that the Mechanically Altered Diet data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the

Mechanically Altered Diet data element to the OASIS, and that HHAs would be required to report these data for the CY 2020 HH QRP at SOC/ROC and discharge between January 1, 2019 and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019, through June 30, 2020 for the CY 2021 HH QRP.

We are inviting public comment on these proposals.

xvi. Nutritional Approach: Therapeutic Diet

We are proposing that the Therapeutic Diet data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data element consists of the single Therapeutic Diet data element. For more information on the Therapeutic Diet data element, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking*, available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html>.

Therapeutic Diet refers to meals planned to increase, decrease, or eliminate specific foods or nutrients in a patient or resident’s diet, such as a low-salt diet, for the purpose of treating a medical condition. The use of therapeutic diets among patients in PAC provides insight on the clinical complexity of these patients and their multiple comorbidities. Therapeutic diets are less resource intensive from the bedside nursing perspective, but can signify one or more underlying clinical conditions that preclude the patient from eating a regular diet. They also often require more education and lifestyle modification training. The communication among PAC providers about whether a patient is receiving a particular therapeutic diet is critical to ensure safe transitions of care.

The Therapeutic Diet data element is currently in use in the MDS 3.0. The testing of similar nutrition-focused data elements in the PAC PRD, and the current assessment of various nutritional services across the four PAC settings, demonstrates the feasibility of collecting information about this nutritional service in these settings.

Clinical and subject matter expert advisors working with our data element contractor supported the importance

²⁰⁷ Dempsey, D.T., Mullen, J.L., & Buzby, G.P. (1988). “The link between nutritional status and clinical outcome: can nutritional intervention modify it?” *Am J of Clinical Nutrition* 47(2): 352–356.

and clinical usefulness of the proposed Therapeutic Diet data element for patients in PAC settings, due to the increased monitoring and resource use required for patients on special diets, and agreed that it is feasible for use in PAC and that it assesses an important treatment that would be clinically useful both within and across PAC settings. We note that the Therapeutic Diet data element was also supported by the TEP that discussed candidate data elements for Special Services, Treatments, and Interventions during a meeting on January 5 and 6, 2017.

Therefore, we are proposing that the Therapeutic Diet data element meets the definition of standardized patient assessment data for special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the Therapeutic Diet data element to the OASIS, and that HHAs would be required to report these data for the CY 2020 HH QRP at SOC/ROC and discharge between January 1, 2019 and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019, through June 30, 2020 for the CY 2021 HH QRP.

We are inviting public comment on these proposals.

d. Medical Condition and Comorbidity Data

We are proposing that the data elements needed to calculate the current measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), and that the proposed measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, meet the definition of standardized patient assessment data with respect to medical conditions and co-morbidities under section 1899B(b)(1)(B)(iv) of the Act, and that the successful reporting of that data under section 1895(b)(3)(B)(v)(IV)(aa) of the Act would also satisfy the requirement to report standardized patient assessment data under section 1895(b)(3)(B)(v)(IV)(bb) of the Act.

“Medical conditions and co-morbidities” and the conditions addressed in the standardized data elements used in the calculation and risk adjustment of these measures, that is, the presence of pressure ulcers, diabetes, incontinence, peripheral vascular disease or peripheral arterial disease, mobility, as well as low body mass index (BMI), are all health-related conditions that indicate medical

complexity that can be indicative of underlying disease severity and other comorbidities.

Specifically, the data elements used in the measure are important for care planning and provide information pertaining to medical complexity. Pressure ulcers are serious wounds representing poor outcomes, and can result in sepsis and death. Assessing skin condition, care planning for pressure ulcer prevention and healing, and informing providers about their presence in patient transitions of care is imperative a customary and best practice. Venous and arterial disease and diabetes are associated with insufficient low blood flow, which may increase the risk of tissue damage. These diseases commonly are indicators of factors that may place individuals at risk for pressure ulcer development and are therefore important for care planning. Low BMI, which may be an indicator of underlying disease severity, may be associated with loss of fat and muscle, resulting in potential risk for pressure ulcers due to shearing. Bowel incontinence, and the possible maceration to the skin associated, can lead to higher risk for pressure ulcers. In addition, the bacteria associated with bowel incontinence can complicate current wounds and cause local infection. Mobility is an indicator of impairment or reduction in mobility and movement which is a major risk factor for the development of pressure ulcers. Taken separately and together, these data elements are important for care planning, transitions in services and identifying medical complexities.

e. Impairment Data

Hearing and vision impairments are conditions that, if unaddressed, affect activities of daily living, communication, physical functioning, rehabilitation outcomes, and overall quality of life. Sensory limitations can lead to confusion in new settings, increase isolation, contribute to mood disorders, and impede accurate assessment of other medical conditions. Failure to appropriately assess, accommodate, and treat these conditions increases the likelihood that patients will require more intensive and prolonged treatment. Onset of these conditions can be gradual, so individualized assessment with accurate screening tools and regular follow-up evaluations are essential to determining which patients need hearing- or vision-specific medical attention or assistive devices, and accommodations, including auxiliary aids and/or services, and to ensure that person-directed care plans are developed to accommodate a

patient's needs. Accurate diagnosis and management of hearing or vision impairment would likely improve rehabilitation outcomes and care transitions, including transition from institutional-based care to the community. Accurate assessment of hearing and vision impairment would be expected to lead to appropriate treatment, accommodations, including the provision of auxiliary aids and services during the stay, and ensure that patients continue to have their vision and hearing needs met when they leave the facility.

Accurate individualized assessment, treatment, and accommodation of hearing and vision impairments of patients and residents in PAC would be expected to have a positive impact on the National Quality Strategy's domains of patient and family engagement, patient safety, care coordination, clinical process/effectiveness, and efficient use of healthcare resources. For example, standardized assessment of hearing and vision impairments used in PAC will support ensuring patient safety (for example, risk of falls) identifying accommodations needed during the stay, and appropriate support needs at the time of discharge or transfer. Standardized assessment of these data elements will enable or support clinical decision-making and early clinical intervention; person-centered, high quality care (for example, facilitating better care continuity and coordination); better data exchange and interoperability between settings; and longitudinal outcome analysis. Hence, reliable data elements assessing hearing and vision impairments are needed to initiate a management program that can optimize a patient or resident's prognosis and reduce the possibility of adverse events.

i. Hearing

We are proposing that the Hearing data element meets the definition of standardized patient assessment data for impairments under section 1899B(b)(1)(B)(v) of the Act. The proposed data element consists of the single Hearing data element. This data element assesses level of hearing impairment, and consists of one question. For more information on the Hearing data element, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking*, available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html>.

Accurate assessment of hearing impairment is important in the PAC setting for care planning and resource use. Hearing impairment has been associated with lower quality of life, including poorer physical, mental, and social functioning, and emotional health.^{208 209} Treatment and accommodation of hearing impairment led to improved health outcomes, including but not limited to increased quality of life.²¹⁰ For example, hearing loss in elderly individuals has been associated with depression and cognitive impairment,^{211 212 213} higher rates of incident cognitive impairment and cognitive decline,²¹⁴ and less time in occupational therapy.²¹⁵ Accurate assessment of hearing impairment is important in the PAC setting for care planning and defining resource use.

The proposed data element was selected from two forms of the Hearing data element based on expert and stakeholder feedback. We considered the two forms of the Hearing data element, one of which is currently in use in the MDS 3.0 (Hearing) and another data element with different wording and fewer response option categories that is currently in use in the OASIS-C2 (Ability to Hear). Ability to Hear was also tested in the PAC PRD and found to have substantial agreement for inter-rater reliability across PAC settings (kappa of 0.78).²¹⁶

²⁰⁸ Dalton DS, Cruickshanks KJ, Klein BE, Klein R, Wiley TL, Nondahl DM. The impact of hearing loss on quality of life in older adults. *Gerontologist*. 2003;43(5):661–668.

²⁰⁹ Hawkins K, Bottone FG, Jr., Ozminkowski RJ, et al. The prevalence of hearing impairment and its burden on the quality of life among adults with Medicare Supplement Insurance. *Qual Life Res*. 2012;21(7):1135–1147.

²¹⁰ Horn KL, McMahon NB, McMahon DC, Lewis JS, Barker M, Gherini S. Functional use of the Nucleus 22-channel cochlear implant in the elderly. *The Laryngoscope*. 1991;101(3):284–288.

²¹¹ Sprinzel GM, Riechelmann H. Current trends in treating hearing loss in elderly people: a review of the technology and treatment options—a mini-review. *Gerontology*. 2010;56(3):351–358.

²¹² Lin FR, Thorpe R, Gordon-Salant S, Ferrucci L. Hearing Loss Prevalence and Risk Factors Among Older Adults in the United States. *The Journals of Gerontology Series A: Biological Sciences and Medical Sciences*. 2011;66A(5):582–590.

²¹³ Hawkins K, Bottone FG, Jr., Ozminkowski RJ, et al. The prevalence of hearing impairment and its burden on the quality of life among adults with Medicare Supplement Insurance. *Qual Life Res*. 2012;21(7):1135–1147.

²¹⁴ Lin FR, Metter EJ, O'Brien RJ, Resnick SM, Zonderman AB, Ferrucci L. Hearing Loss and Incident Dementia. *Arch Neurol*. 2011;68(2):214–220.

²¹⁵ Cimarolli VR, Jung S. Intensity of Occupational Therapy Utilization in Nursing Home Residents: The Role of Sensory Impairments. *J Am Med Dir Assoc*. 2016;17(10):939–942.

²¹⁶ Gage B., Smith L., Ross J. et al. (2012). The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set

Several data elements that assess hearing impairment were presented to the Standardized Patient Assessment Data TEP held by our data element contractor. The TEP did not reach consensus on the ideal number of response categories or phrasing of response options, which are the primary differences between the current MDS (Hearing) and OASIS (Ability to Hear) items. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data Technical Expert Panel Summary Report is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

The PAC PRD form of the data element (Ability to Hear) was included in a call for public comment that was open from August 12 to September 12, 2016. This data element includes three response choices, in contrast to the Hearing data element (in use in the MDS 3.0 and being proposed for standardization), which includes four response choices. Several commenters supported the use of the Ability to Hear data element, although some commenters raised concerns that the three-level response choice was not compatible with the current, four-level response used in the MDS, and favored the use of the MDS version of the Hearing data element. In addition, we received comments stating that standardized assessment related to hearing impairment has the ability to improve quality of care if information on hearing is included in medical records of patients and residents, which would improve care coordination and facilitate the development of patient- and resident-centered treatment plans. Based on comments that the three-level response choice (Ability to Hear) was not congruent with the current, four-level response used in the MDS (Hearing), and support for the use of the MDS version of the Hearing data element received in the public comment, we are proposing the Hearing data element from the MDS. A full report of the comments is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Therefore, we are proposing the Hearing data element currently in use in

(Final Report on Reliability Testing, Volume 2 of 3). Research Triangle Park, NC: RTI International.

the MDS. We are proposing to add the Hearing data element to the OASIS, and that HHAs would be required to report these data for the CY 2020 HH QRP at SOC/ROC between January 1, 2019 and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019, through June 30, 2020 for the CY 2021 HH QRP. The Hearing data element would be assessed at SOC/ROC only due to the relatively stable nature of hearing impairment, making it unlikely that this assessment would change between the start and end of care. Assessment at discharge would introduce additional burden without improving the quality or usefulness of the data, and we believe it is unnecessary.

We are inviting public comment on these proposals.

ii. Vision

We are proposing that the Vision data element meets the definition of standardized patient assessment data for impairments under section 1899B(b)(1)(B)(v) of the Act. The proposed data element consists of the single Vision (Ability To See in Adequate Light) data element that consists of one question with five response categories. For more information on the Vision data element, we refer readers to the document titled, *Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rulemaking*, available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html>.

Evaluation of an individual's ability to see is important for assessing for risks such as falls and provides opportunities for improvement through treatment and the provision of accommodations, including auxiliary aids and services, which can safeguard patients and improve their overall quality of life. Further, vision impairment is often a treatable risk factor associated with adverse events and poor quality of life. For example, individuals with visual impairment are more likely to experience falls and hip fracture, have less mobility, and report depressive symptoms.^{217 218 219 220 221 222 223}

²¹⁷ Colon-Emeric CS, Biggs DP, Schenck AP, Lyles KW. Risk factors for hip fracture in skilled nursing facilities: who should be evaluated? *Osteoporos Int*. 2003;14(6):484–489.

²¹⁸ Freeman EE, Munoz B, Rubin G, West SK. Visual field loss increases the risk of falls in older

Individualized initial screening can lead to life-improving interventions such as accommodations, including the provision of auxiliary aids and services, during the stay and/or treatments that can improve vision and prevent or slow further vision loss. For patients with some types of visual impairment, use of glasses and contact lenses can be effective in restoring vision.²²⁴ Other conditions, including glaucoma²²⁵ and age-related macular degeneration,^{226–227} have responded well to treatment. Accurate assessment of vision impairment is important in the PAC setting for care planning and defining resource use.

The Vision data element that we are proposing for standardization was tested as part of the development of the MDS 3.0 and is currently in use in that assessment. Similar data elements, but with different wording and fewer response option categories, are in use in the OASIS–C2 and were tested in post-acute providers in the PAC PRD and found to be clinically relevant, meaningful for care planning, reliable (kappa of 0.74),²²⁸ and feasible for use in each of the four PAC settings.

adults: the Salisbury eye evaluation. *Invest Ophthalmol Vis Sci.* 2007;48(10):4445–4450.

²¹⁹ Keepnews D, Capitman JA, Rosati RJ. Measuring patient-level clinical outcomes of home health care. *J Nurs Scholarsh.* 2004;36(1):79–85.

²²⁰ Nguyen HT, Black SA, Ray LA, Espino DV, Markides KS. Predictors of decline in MMSE scores among older Mexican Americans. *J Gerontol A Biol Sci Med Sci.* 2002;57(3):M181–185.

²²¹ Prager AJ, Liebmann JM, Cioffi GA, Blumberg DM. Self-reported Function, Health Resource Use, and Total Health Care Costs Among Medicare Beneficiaries With Glaucoma. *JAMA ophthalmology.* 2016;134(4):357–365.

²²² Rovner BW, Ganguli M. Depression and disability associated with impaired vision: the MoVies Project. *J Am Geriatr Soc.* 1998;46(5):617–619.

²²³ Tinetti ME, Ginter SF. The nursing home life-space diameter. A measure of extent and frequency of mobility among nursing home residents. *J Am Geriatr Soc.* 1990;38(12):1311–1315.

²²⁴ Rein DB, Wittenborn JS, Zhang X, et al. The Cost-effectiveness of Welcome to Medicare Visual Acuity Screening and a Possible Alternative Welcome to Medicare Eye Evaluation Among Persons Without Diagnosed Diabetes Mellitus. *Archives of ophthalmology.* 2012;130(5):607–614.

²²⁵ Leske M, Heijl A, Hussein M, et al. Factors for glaucoma progression and the effect of treatment: The early manifest glaucoma trial. *Archives of Ophthalmology.* 2003;121(1):48–56.

²²⁶ Age-Related Eye Disease Study Research G. A randomized, placebo-controlled, clinical trial of high-dose supplementation with vitamins c and e, beta carotene, and zinc for age-related macular degeneration and vision loss: AREDS report no. 8. *Archives of Ophthalmology.* 2001;119(10):1417–1436.

²²⁷ Takeda AL, Colquitt J, Clegg AJ, Jones J. Pegaptanib and ranibizumab for neovascular age-related macular degeneration: a systematic review. *The British Journal of Ophthalmology.* 2007;91(9):1177–1182.

²²⁸ Gage B., Smith L., Ross J. et al. (2012). The Development and Testing of the Continuity

Several data elements that assess vision were presented to the TEP held by our data element contractor. The TEP did not reach consensus on the ideal number of response categories or phrasing of response options, which are the primary differences between the current MDS and OASIS items; some members preferring more granular response options (for example, mild impairment and moderate impairment) while others were comfortable with collapsed response options (that is, mild/moderate impairment). The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data Technical Expert Panel Summary Report is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We solicited public comment from August 12 to September 12, 2016, on the Ability to See in Adequate Light data element (version tested in the PAC PRD with three response categories). The data element in public comment differed from the proposed data element, but the comments supported the assessment of vision in PAC settings and the useful information a vision data element would provide. The commenters stated that the Ability to See item would provide important information that would facilitate care coordination and care planning, and consequently improve the quality of care. Other commenters suggested it would be helpful as an indicator of resource use and noted that the item would provide useful information about the abilities of patients and residents to care for themselves. Additional commenters noted that the item could feasibly be implemented across PAC providers and that its kappa scores from the PAC PRD support its validity. Some commenters noted a preference for MDS version of the Vision data element over the form put forward in public comment, citing the widespread use of this data element. A full report of the comments is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

Clinical and subject matter expert advisors working with our data element contractor agreed that assessing vision

Assessment Record and Evaluation (CARE) Item Set (Final Report on Reliability Testing, Volume 2 of 3). Research Triangle Park, NC: RTI International.

impairment of patients and residents with a standardized data element is feasible in PAC, that it can reliably and accurately identify adults with objective impaired vision, and that this information about impaired vision would be clinically useful to identify needed accommodations and/or treatment both within and across PAC settings.

Therefore, we are proposing the Vision data element from the MDS. We are proposing to add the Vision data element to the OASIS, and that HHAs would be required to report these data for the CY 2020 HH QRP at the start of care between January 1, 2019 and June 30, 2019. Following the initial two quarters of reporting for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2019 through June 30, 2020 for the CY 2021 HH QRP. The Vision data element would be assessed at start of care only due to the relatively stable nature of vision impairment, making it unlikely that this assessment would change between the start and end of care. Assessment at the end of care would introduce additional burden without improving the quality or usefulness of the data, and we believe it is unnecessary.

We are inviting public comment on these proposals.

I. Proposals Relating to the Form, Manner, and Timing of Data Submission Under the HH QRP

1. Proposed Start Date for Reporting Standardized Patient Assessment Data by New HHAs

In the CY 2016 HH PPS final rule (80 FR 68624), we adopted timing for new HHAs to begin reporting standardized quality data under the HH QRP. We are proposing in this proposed rule that new HHAs will be required to begin reporting standardized patient assessment data on the same schedule. We are inviting public comment on this proposal.

2. Proposed Mechanism for Reporting Standardized Patient Assessment Data Beginning With the CY 2019 HH QRP

Under our current policy, HHAs report data by completing applicable sections of the OASIS, and submitting the OASIS to CMS through the QIES, ASAP system. For more information on HH QRP reporting through the QIES ASAP system, refer to <https://www.qiso.com/index.php>. In addition to the data currently submitted on quality measures as previously finalized and described in Table 49 of this proposed

rule, we are proposing that HHAs would be required to begin submitting the proposed standardized patient assessment data for HHA Medicare and Medicaid quality episodes that begin or end on or after January 1, 2019 using the OASIS, as described here.

Further, the proposed standardized patient assessment data elements described above would be added to the OASIS, so the new reporting requirements regarding those elements would result in no changes to the mechanism by which HHAs report data under the HH QRP. All standardized patient assessment data elements would be collected at SOC/ROC using the OASIS item set, and all except the Brief Interview for Mental Status (BIMS), Hearing, and Vision data elements are or would be collected at discharge using the OASIS item set. Details on the modifications and assessment collection

for the OASIS for the proposed standardized data are available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html>.

We are inviting public comments on these proposals.

3. Proposed Schedule for Reporting Standardized Patient Assessment Data Beginning With the CY 2019 HH QRP

Starting with the CY 2019 HH QRP, we are proposing to apply our current schedule for the reporting of measure data to the reporting of standardized patient assessment data. Under that policy, except for the first program year for which a measure is adopted, HHAs must report data on measures for HHA Medicare and Medicaid quality episodes that occur during the 12-month period (between July 1 and June 30) that

applies to the program year. For the first program year for which a measure is adopted, HHAs are only required to report data on HHA Medicare and Medicaid quality episodes that begin on or after January 1 and end up to and including June 30 of the calendar year that applies to that program year. For example, for the CY 2019 HH QRP, data on measures adopted for earlier program years must be reported for all HHA Medicare and Medicaid quality episodes that begin on or after July 1, 2017 and end on or before June 30, 2018. However, data on new measures adopted for the first time for the CY 2019 HH QRP program year must only be reported for HHA Medicare and Medicaid quality episodes that begin or end during the first two quarters of CY 2018. Tables 49 and 50 illustrate this policy.

TABLE 49—SUMMARY ILLUSTRATION OF INITIAL REPORTING FOR NEWLY ADOPTED MEASURES AND STANDARDIZED PATIENT ASSESSMENT DATA REPORTING USING CY Q1 AND Q2 DATA FOR THE HH QRP *

Proposed data collection/submission reporting period *	Proposed data submission deadlines beginning with CY 2019 HH QRP *
January 1, 2018–June 30, 2018	July 31, 2018.

* We note that submission of the OASIS must also adhere to the HH PPS deadlines.

^ The term “CY 2019 HH QRP” means the calendar year for which the HH QRP requirements applicable to that calendar year must be met in order for a HHA to avoid a two percentage point reduction to its market basket percentage when calculating the payment rates applicable to it for that calendar year.

TABLE 50—SUMMARY ILLUSTRATION OF OASIS 12 MONTH DATA REPORTING FOR MEASURES AND STANDARDIZED PATIENT ASSESSMENT DATA REPORTING FOR THE HH QRP *

Proposed data collection/submission reporting period *	Proposed data submission deadlines beginning with CY 2020 HH QRP * ^
July 1, 2018–June 30, 2019	July 31, 2019.

* We note that submission of the OASIS must also adhere to the HH PPS deadlines.

^ The term “CY 2020 HH QRP” means the calendar year for which the HH QRP requirements applicable to that calendar year must be met in order for a HHA to avoid a two percentage point reduction to its market basket percentage when calculating the payment rates applicable to it for that calendar year.

We are inviting comment on our proposal to extend our current policy governing the schedule for reporting the quality measure data to the reporting of standardized patient assessment data for the HH QRP beginning with the CY 2019 HH QRP.

4. Proposed Schedule for Reporting the Proposed Quality Measures Beginning With the CY 2020 HH QRP

As discussed in section V.I. of this proposed rule, we are proposing to adopt three quality measures beginning with the CY 2020 HH QRP: Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury; Application of The Percent of Residents Experiencing One or More Falls with Major Injury (NQF # 0674); and Application of Percent of Long-Term Care Hospital Patients with an

Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631). We are proposing that HHAs would report data on these measures using OASIS reporting that is submitted through the QIES ASAP system. More information on OASIS reporting using the QIES ASAP system is located at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/OASIS/Data Specifications.html>.

For the CY 2020 HH QRP, HHAs would be required to report these data for HHA Medicare and Medicaid quality episodes that begin or end during the period from January 1, 2019 to June 30, 2019. Beginning with the CY 2021 HH QRP, HHAs would be required to submit data for the entire 12-month

period from July 1 to June 30. Further, for the purposes of measure calculation, our policy was established in the CY 2017 HH PPS final rule (81 FR 76702) that data are utilized using calendar year timeframes with review and correction periods.

We are inviting public comment on this proposal.

5. Input Sought for Data Reporting Related to Assessment Based Measures

Through various means of public input, including through previous rules, public comment on measures, and the MAP, we have received input suggesting that we expand the population for quality measurement to include all patients regardless of payer. Approximately 75 percent of home health expenditures in 2014 were made

by either Medicare or Medicaid and currently both Medicare and Medicaid collect and report data for OASIS. We believe that expanding the patient population for which OASIS collects data will allow us to ensure data that is representative of quality provided to all patients in the HHA setting and therefore allow us to better determine whether HH Medicare beneficiaries receive the same quality of care that other patients receive. We also appreciate that collecting quality data on all patients regardless of payer source may create additional burden. However, we also received input that the effort to separate out Medicare and Medicaid beneficiaries, who are currently reported through OASIS, from other patients creates clinical and work flow implications with an associated burden too, and we further appreciate that it is common practice for HHAs to collect OASIS data on all patients, regardless of payer source. Thus, we are seeking input on whether we should require quality data reporting on all HH patients, regardless of payer, where feasible—noting that because Medicare Part A claims data are submitted only with respect to Medicare beneficiaries, claims-based measures rates would continue to be calculated only for Medicare beneficiaries.

We are inviting public comments on this topic.

J. Other Proposals for the CY 2019 HH QRP and Subsequent Years

1. Proposal To Apply the HH QRP Data Completion Thresholds to the Submission of Standardized Patient Assessment Data Beginning With the CY 2019 HH QRP

In the CY 2016 HH PPS final rule (80 FR 68703 through 68705), we defined the pay-for-reporting performance system model that could accurately measure the level of an HHA's submission of OASIS data based on the principle that each HHA is expected to submit a minimum set of two matching assessments for each patient admitted to their agency. These matching assessments together create what is considered a quality episode of care, consisting ideally of a Start of Care (SOC) or Resumption of Care (ROC) assessment and a matching End of Care (EOC) assessment. EOC assessments comprise the Discharge from Agency, Death at Home and Transfer to an Inpatient Facility time points. For further information on successful submission of OASIS assessments, types of assessments submitted by an HHA that fit the definition of a quality assessment, defining the "Quality

Assessments Only" (QAO) formula, and implementing a pay-for-reporting performance requirement over a 3-year period, please see the CY 2016 HH PPS final rule (80 FR 68704 to 68705).

Additionally, we finalized the pay-for-reporting threshold requirements in the CY 2016 HH PPS rule. We finalized a policy through which HHAs must score at least 70 percent on the QAO metric of pay-for-reporting performance requirement for CY 2017 (reporting period July 1, 2015 to June 30, 2016), 80 percent for CY 2018 (reporting period July 1, 2016 to June 30, 2017) and 90 percent for CY 2019 (reporting period July 1, 2017 to June 30, 2018). An HHA that does not meet this requirement for a calendar year will be subject to a two percentage point reduction to the market basket percentage increase that would otherwise apply for that calendar year. We are now proposing to apply the threshold requirements established in the CY 2016 HH PPS rule to the submission of standardized patient assessment data beginning with the CY 2019 HH QRP.

We are inviting public comment on our proposal to extend our current HH QRP data completion requirements to the submission of standardized patient assessment data.

2. Proposal for the HH QRP Submission Exception and Extension Requirements

Our experience with other QRPs has shown that there are times when providers are unable to submit quality data due to extraordinary circumstances beyond their control (for example, natural, or man-made disasters). Other extenuating circumstances are reviewed on a case-by-case basis. We propose to define a "disaster" as any natural or man-made catastrophe which causes damages of sufficient severity and magnitude to partially or completely destroy or delay access to medical records and associated documentation. Natural disasters could include events such as hurricanes, tornadoes, earthquakes, volcanic eruptions, fires, mudslides, snowstorms, and tsunamis. Man-made disasters could include such events as terrorist attacks, bombings, floods caused by man-made actions, civil disorders, and explosions. A disaster may be widespread and impact multiple structures or be isolated and impact a single site only.

In certain instances of either natural or man-made disasters, an HHA may have the ability to conduct a full patient assessment, and record and save the associated data either during or before the occurrence of the extraordinary event. In this case, the extraordinary event has not caused the agency's data

files to be destroyed, but it could hinder the HHA's ability to meet the QRP's data submission deadlines. In this scenario, the HHA would potentially have the ability to report the data at a later date, after the emergency has passed. In such cases, a temporary extension of the deadlines for reporting might be appropriate.

In other circumstances of natural or man-made disaster, an HHA may not have had the ability to conduct a full patient assessment, or to record and save the associated data before the occurrence of the extraordinary event. In such a scenario, the agency may not have complete data to submit to CMS. We believe that it may be appropriate, in these situations, to grant a full exception to the reporting requirements for a specific period of time.

We do not wish to penalize HHAs in these circumstances or to unduly increase their burden during these times. Therefore, we propose a process for HHAs to request and for us to grant exceptions and extensions for the reporting requirements of the HH QRP for one or more quarters, beginning with the CY 2019 HH QRP, when there are certain extraordinary circumstances beyond the control of the HHA. When an exception or extension is granted, we would not reduce the HHA's PPS payment for failure to comply with the requirements of the HH QRP.

We propose that if an HHA seeks to request an exception or extension for the HH QRP, the HHA should request an exception or extension within 90 days of the date that the extraordinary circumstances occurred. The HHA may request an exception or extension for one or more quarters by submitting a written request to CMS that contains the information noted below, via email to the HHA Exception and Extension mailbox at HHAPureConsiderations@cms.hhs.gov. Requests sent to CMS through any other channel would not be considered as valid requests for an exception or extension from the HH QRP's reporting requirements for any payment determination.

The subject of the email must read "HH QRP Exception or Extension Request" and the email must contain the following information:

- HHA CCN;
- HHA name;
- CEO or CEO-designated personnel contact information including name, telephone number, email address, and mailing address (the address must be a physical address, not a post office box);
- HHA's reason for requesting an exception or extension;
- Evidence of the impact of extraordinary circumstances, including

but not limited to photographs, newspaper and other media articles; and

- A date when the HHA believes it will be able to again submit HH QRP data and a justification for the proposed date.

We propose that exception and extension requests be signed by the HHA's CEO or CEO-designated personnel, and that if the CEO designates an individual to sign the request, the CEO-designated individual has the appropriate authority to submit such a request on behalf of the HHA. Following receipt of the email, we would: (1) Provide a written acknowledgement, using the contact information provided in the email, to the CEO or CEO-designated contact notifying them that the request has been received; and (2) provide a formal response to the CEO or any CEO-designated HHA personnel, using the contact information provided in the email, indicating our decision.

This proposal does not preclude us from granting exceptions or extensions to HHAs that have not requested them when we determine that an extraordinary circumstance, such as an act of nature, affects an entire region or locale. If we make the determination to grant an exception or extension to all HHAs in a region or locale, we propose to communicate this decision through routine communication channels to HHAs and vendors, including, but not limited to, issuing memos, emails, and notices on our HH QRP Web site once it is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HomeHealthQualityReporting-Reconsideration-and-Exception-and-Extension.html>.

We also propose that we may grant an exception or extension to HHAs if we determine that a systemic problem with one of our data collection systems directly affected the ability of the HHA to submit data. Because we do not anticipate that these types of systemic errors will happen often, we do not anticipate granting an exception or extension on this basis frequently.

If an HHA is granted an exception, we would not require that the HHA submit any measure data for the period of time specified in the exception request decision. If we grant an extension to the original submission deadline, the HHA would still remain responsible for submitting quality data collected during the timeframe in question, although we would specify a revised deadline by which the HHA must submit this quality data.

We also propose that any exception or extension requests submitted for

purposes of the HH QRP would apply to that program only, and not to any other program we administer for HHAs such as survey and certification. OASIS requirements, including electronic submission, during Declared Public Health Emergencies can be found at FAQs I-5, I-6, I-7, I-8 at <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/downloads/AllHazardsFAQs.pdf>.

We intend to provide additional information pertaining to exceptions and extensions for the HH QRP, including any additional guidance, on the HH QRP Web site at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HomeHealthQualityReporting-Reconsideration-and-Exception-and-Extension.html>.

We propose to add the HH QRP Submission Exception and Extension Requirements at § 484.250(d). We welcome comment on these proposals.

3. Proposed HH QRP Submission Reconsideration and Appeals Procedures

The HH QRP reconsiderations and appeals process was finalized in the CY 2013 HH PPS final rule (77 FR 67096) and has been used for prior all periods cited in the previous rules, and utilized in the CY 2012 to CY 2017 APU determinations. At the conclusion of the required quality data reporting and submission period, we review the data received from each HHA during that reporting period to determine if the HHA met the HH QRP reporting requirements. HHAs that are found to be noncompliant with the HH QRP reporting requirements for the applicable calendar year will receive a 2 percentage point reduction to its market basket percentage update for that calendar year.

Similar to our other quality reporting programs, such as the SNF QRP, the LTCH QRP, and the IRF QRP, we include an opportunity for the providers to request a reconsideration of our initial noncompliance determination. To be consistent with other established quality reporting programs and to provide an opportunity for HHAs to seek reconsideration of our initial noncompliance decision, we are proposing a process that enables an HHA to request reconsideration of our initial non-compliance decision in the event that it believes that it was incorrectly identified as being non-compliant with the HH QRP reporting requirements for a particular calendar year. These proposals clarify the HH

QRP reconsiderations and appeals process that we have finalized in previous rules.

For the CY 2019 HH QRP, and subsequent years, we are proposing that a HHA would receive a notification of noncompliance if we determine that the HHA did not submit data in accordance with the HH QRP reporting requirements for the applicable CY. The purpose of this notification is to put the HHA on notice that the HHA: (1) Has been identified as being non-compliant with the HH QRP's reporting requirements for the applicable calendar year; (2) will be scheduled to receive a reduction in the amount of two percentage points to its market basket percentage update for the applicable calendar year; (3) may file a request for reconsideration if it believes that the finding of noncompliance is erroneous, has submitted a request for an extension or exception that has not yet been decided, or has been granted an extension or exception; and (4) must follow a defined process on how to file a request for reconsideration, which will be described in the notification. We would only consider requests for reconsideration after an HHA has been found to be noncompliant.

Notifications of noncompliance and any subsequent notifications from CMS would be sent via a traceable delivery method, such as certified U.S. mail or registered U.S. mail, or through other practicable notification processes, such as a report from CMS to the provider as a Certification and Survey Provider Enhanced Reports (CASPER) report, that will provide information pertaining to their compliance with the reporting requirements for the given reporting cycle or from the Medicare Administrative Contractors assigned to process the provider's claims. To obtain the compliance reports, providers should access the CASPER Reporting Application. HHA providers access the CASPER Reporting application via their CMS OASIS System Welcome page by selecting the CASPER Reporting link. The "CASPER Reports" link will connect an HHA to the QIES National System Login page for CASPER Reporting.

We propose to disseminate communications regarding the availability of compliance reports through routine channels to HHAs and vendors, including, but not limited to issuing memos, emails, Medicare Learning Network (MLN) announcements, and notices on our HH QRP Web site once it is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/>

HomeHealthQualityReporting-Reconsideration-and-Exception-and-Extension.html.

An HHA would have 30 days from the date of the letter of noncompliance to submit to us a request for reconsideration. This proposed time frame allows us to balance our desire to ensure that HHAs have the opportunity to request reconsideration with our need to complete the process and provide HHAs with our reconsideration decision in a timely manner. We are proposing that an HHA may withdraw its request at any time and may file an updated request within the proposed 30-day deadline. We are also proposing that, in very limited circumstances, we may grant a request by an HHA to extend the proposed deadline for reconsideration requests. It would be the responsibility of an HHA to request an extension and demonstrate that extenuating circumstances existed that prevented the filing of the reconsideration request by the proposed deadline.

We also are proposing that as part of the HHA's request for reconsideration, the HHA would be required to submit all supporting documentation and evidence demonstrating full compliance with all HH QRP reporting requirements for the applicable calendar year, that the HHA has requested an extension or exception for which a decision has not yet been made, that the HHA has been granted an extension or exception, or has experienced an extenuating circumstance as defined in section V.I.2 of this rule but failed to file a timely request of exception. We propose that we would not review any reconsideration request that fails to provide the necessary documentation and evidence along with the request.

The documentation and evidence may include copies of any communications that demonstrate the HHA's compliance with the HH QRP, as well as any other records that support the HHA's rationale for seeking reconsideration, but should not include any protected health information (PHI). We intend to provide a sample list of acceptable supporting documentation and evidence, as well as instructions for HHAs on how to retrieve copies of the data submitted to CMS for the appropriate program year in the future on our HH QRP Web site at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HomeHealthQualityReporting-Reconsideration-and-Exception-and-Extension.html>.

We are proposing that an HHA wishing to request a reconsideration of our initial noncompliance determination would be required to do

so by submitting an email to the following email address: HHAPureConsiderations@cms.hhs.gov.

Any request for reconsideration submitted to us by an HHA would be required to follow the guidelines outlined on our HH QRP Web site once it is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HomeHealthQualityReporting-Reconsideration-and-Exception-and-Extension.html>.

All emails must contain a subject line that reads "HH QRP Reconsideration Request." Electronic email submission is the only form of reconsideration request submission that will be accepted by us. Any reconsideration requests communicated through another channel including, but not limited to, U.S. Postal Service or phone, will not be considered as a valid reconsideration request.

We are proposing that a reconsideration request include the following information:

- HHA CMS Certification Number (CCN);
- HHA Business Name;
- HHA Business Address;
- The CEO contact information including name, email address, telephone number and physical mailing address; or The CEO-designated representative contact information including name, title, email address, telephone number and physical mailing address; and
- CMS identified reason(s) for noncompliance from the non-compliance notification; and
- The reason(s) for requesting reconsideration.

The request for reconsideration must be accompanied by supporting documentation demonstrating compliance. Following receipt of a request for reconsideration, we would provide an email acknowledgment, using the contact information provided in the reconsideration request, to the CEO or CEO-designated representative that the request has been received. Once we have reached a decision regarding the reconsideration request, an email would be sent to the HHA CEO or CEO designated representative, using the contact information provided in the reconsideration request, notifying the HHA of our decision.

We also propose that the notifications of our decision regarding reconsideration requests may be made available through a traceable delivery method, such as certified U.S. mail or registered U.S. mail or through the use of CASPER reports. If the HHA is dissatisfied with the decision rendered at the reconsideration level, the HHA

may appeal the decision to the PRRB under 42 CFR 405.1835. We believe this proposed process is more efficient and less costly for CMS and for HHAs because it decreases the number of PRRB appeals by resolving issues earlier in the process. Additional information about the reconsideration process including details for submitting a reconsideration request will be posted in the future to our HH QRP Web site at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HomeHealthQualityReporting-Reconsideration-and-Exception-and-Extension.html>.

We propose to add the HH QRP Submission Reconsideration and Appeals Procedures at § 484.250(e) and (f). We welcome comment on these proposals.

K. Proposals and Policies Regarding Public Display of Quality Measure Data for the HH QRP

Our home health regulations, at § 484.250(a), require HHAs to submit OASIS assessments and Home Health Care Consumer Assessment of Healthcare Providers and Systems Survey® (HCAHPS) data to meet the quality reporting requirements of section 1895(b)(3)(B)(v) of the Act. Section 1899B(g) of the Act requires that data and information of provider performance on quality measures and resource use and other measures be made publicly available beginning not later than two years after the applicable specified "application date". In addition, sections 1895(b)(3)(B)(v)(III) requires the Secretary to establish procedures for making data submitted under section 1895(b)(3)(B)(v)(II) available to the public, and section 1899B(g)(1) of the Act requires the Secretary to do the same with respect to HHA performance on measures specified under sections 1899B(c)(1) and (d)(1) of the Act. Section 1895(b)(3)(B)(v)(III) of the Act requires that the public reporting procedures for data submitted under subclause (II) ensure that a HHA has the opportunity to review the data that is to be made public with respect to it prior to such data being made public. Under section 1899B(g)(2) of the Act, the public reporting procedures for performance on measures under sections 1899B(c)(1) and (d)(1) of the Act must ensure, including through a process consistent with the process applied under section 1886(b)(3)(B)(viii)(VII) of the Act, (which refers to public display and review requirements in the Hospital Inpatient Quality Reporting (Hospital IQR) Program), that a HHA has the

opportunity to review and submit corrections to its data and information that are to be made public for the agency prior to such data being made public. We recognize that public reporting of quality data is a vital component of a robust quality reporting program and are fully committed to ensuring that the data made available to the public are meaningful. Further, we agree that measures for comparing performance across home health agencies should be constructed from data collected in a standardized and uniform manner.

In the CY 2017 HH PPS final rule (81 FR 76785 through 76786), we finalized procedures that allow individual HHAs to review and correct their data and information on IMPACT Act measures that are to be made public before those measure data are made public. Information on how to review and correct data on IMPACT Act measures that are to be made public before those measure data are made public can be found on the HH QRP Web site at [https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Reporting-](https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Reporting-Requirements.html)

[Requirements.html](https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Reporting-Requirements.html). We are not proposing any changes to these policies.

In this CY 2018 HH PPS proposed rule, pending the availability of data, we are proposing to publicly report data beginning in CY 2019 for the following two assessment-based measures: (1) Percent of Patients or Residents with Pressure Ulcers that are New or Worsened (NQF #0678); and (2) Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP. Data collection for these two assessment-based measures began on OASIS on January 1, 2017. We propose to publicly report data beginning in CY 2019 for these assessment-based measures based on four rolling quarters of data, beginning with data collected for discharges in 2017.

In addition, we are proposing to publicly report data beginning in CY 2019 for the following 3 claims-based measures: (1) Medicare Spending Per Beneficiary-PAC HH QRP; (2) Discharge to Community-PAC HH QRP; and (3) Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP. As adopted in the CY 2017 HH PPS final rule (81 FR 43773), for the MSPB-PAC HH QRP measure, we will

use one year of claims data beginning with CY 2016 claims data to inform confidential feedback reports for HHAs, and CY 2017 claims data for public reporting for the HH QRP. For the Discharge to Community—PAC HH QRP measure we will use 2 years of claims data, beginning with CYs 2015 and 2016 claims data to inform confidential feedback and CYs 2016 and 2017 claims data for public reporting. For the Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP, we will use 3 years of claims data, beginning with CY 2014, 2015 and 2016 claims data to inform confidential feedback reports for HHAs, and CY 2015, 2016 and 2017 claims data for public reporting.

Finally, we are proposing to assign HHAs with fewer than 20 eligible cases during a performance period to a separate category: “The number of patient episodes for this measure is too small to report,”²²⁹ to ensure the statistical reliability of the measures. If a HHA had fewer than 20 eligible cases, the HHA’s performance would not be publicly reported for the measure for that performance period.

TABLE 51—SUMMARY OF PROPOSED NEW HH QRP MEASURES FOR CY 2019 PUBLIC DISPLAY

Proposed Measures:

- Percent of Residents or Patients with Pressure Ulcers that Are New or Worsened (Short Stay) (NQF #0678).
- Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP.
- Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP.
- Discharge to Community—(PAC) HH QRP.
- Medicare Spending Per Beneficiary (PAC) HH QRP.

We are inviting public comment on these proposals for the public display of quality data, as described in this proposed rule.

L. Proposed Mechanism for Providing Confidential Feedback Reports to HHAs

Section 1899B(f) of the Act requires the Secretary to provide confidential feedback reports to post-acute care (PAC) providers on their performance on the measures specified under subsections (c)(1) and (d)(1) of section 1899B of the Act, beginning one year after the specified application date that applies to such measures and PAC providers. In the CY 2017 HH PPS final rule (81 FR 76702), we finalized processes to allow HH providers the opportunity to review their data and information using confidential feedback reports that will enable HHAs to review their performance on the measures required under the HH QRP.

Information on how to obtain these and other reports available to the HH QRP can be found at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Reporting-Requirements.html>. We are not proposing any changes to this policy.

M. Home Health Care CAHPS® Survey (HHCAHPS)

In the CY 2017 HH PPS final rule (81 FR 76787), we stated that the home health quality measures reporting requirements for Medicare-certified agencies includes the Home Health Care CAHPS® (HHCAHPS) Survey for the Home Health Quality Reporting Program and along with OASIS measures, HHCAHPS participation is required for the Annual Payment Update (APU). In the CY 2017 HH PPS final rule, we finalized the reporting requirements and

the data submission dates for the CY 2017–CY 2020 APU periods. We proposed to continue the HHCAHPS requirements in future years for the continuous monthly data collection and quarterly data submission of HHCAHPS data.

1. Background and Description of HHCAHPS

The HHCAHPS survey is part of a family of CAHPS® surveys that asks patients to report on and rate their experiences with health care. For more details about the HH CAHPS Survey please see 81 FR 76787 through 76788.

We stated in previous rules that Medicare-certified HHAs are required to contract with an approved HHCAHPS survey vendor. This requirement continues, and Medicare-certified agencies are required to provide a monthly list of their HHCAHPS-eligible patients to their respective HHCAHPS

²²⁹ This language is currently available as Footnote #4 on Home Health Compare ([https://](https://www.medicare.gov/HomeHealthCompare/Data/Footnotes.html)

www.medicare.gov/HomeHealthCompare/Data/Footnotes.html).

survey vendors. Home health agencies are not allowed to influence their patients about how the HHCAHPS survey.

As previously required, new HHCAHPS survey vendors are required to attend Introduction training, and current HHCAHPS vendors are required to attend Update training conducted by CMS and the HHCAHPS Survey Coordination Team. New HHCAHPS vendors need to pass a post-training certification test. We have approximately 30 approved HHCAHPS survey vendors. The list of approved HHCAHPS survey vendors is available at <https://homehealthcahps.org>.

2. HHCAHPS Oversight Activities

We stated in prior final rules that all approved HHCAHPS survey vendors are required to participate in HHCAHPS oversight activities to ensure compliance with HHCAHPS protocols, guidelines, and survey requirements. The purpose of the oversight activities is to ensure that approved HHCAHPS survey vendors follow the *HHCAHPS Protocols and Guidelines Manual*.

In the CY 2013 HH PPS final rule (77 FR 67094, 67164), we codified the current guideline that all approved HHCAHPS survey vendors fully comply with all HHCAHPS oversight activities. We included this survey requirement at § 484.250(c)(3).

For the sake of continuity with this proposed rule, we are reiterating the HHCAHPS requirements for CY 2019, because participation occurs in the period of the publication of the proposed and final rules for CY 2018. We are additionally presenting the HHCAHPS requirements for CY 2020 for the sake of continuity. We are proposing the HHCAHPS requirements for the CY 2021 Annual Payment Update.

3. HHCAHPS Requirements for the CY 2019 HH QRP

In the CY 2017 HH PPS final rule, we finalized the requirements for the CY 2019 HH QRP. For the CY 2019 HH QRP, we require continuous monthly HHCAHPS data collection and reporting for four quarters. The data collection period for the CY 2018 HH QRP includes the second quarter 2017 through the first quarter 2018 (the months of April 2017 through March 2018). HHAs will be required to submit their HHCAHPS data files to the HHCAHPS Data Center for the second quarter 2017 by 11:59 p.m., eastern daylight time (e.d.t.) on October 19, 2017; for the third quarter 2017 by 11:59 p.m., eastern standard time (e.s.t.) on January 18, 2018; for the fourth quarter 2017 by 11:59 p.m., e.d.t. on April 19,

2018; and for the first quarter 2018 by 11:59 p.m., e.d.t. on July 19, 2018. These deadlines are firm; no exceptions will be permitted.

For more details on the CY 2019 HH QRP, we refer readers to 81 FR 76789.

4. HHCAHPS Requirements for the CY 2020 HH QRP

In the CY 2017 HH PPS final rule, we finalized the requirements for the CY 2020 HH QRP. For the CY 2020 HH QRP, we require continued monthly HHCAHPS data collection and reporting for four quarters. The data collection period for the CY 2020 HH QRP includes the second quarter 2018 through the first quarter 2019 (the months of April 2018 through March 2019). HHAs will be required to submit their HHCAHPS data files to the HHCAHPS Data Center for the second quarter 2018 by 11:59 p.m., e.d.t. on October 18, 2018; for the third quarter 2018 by 11:59 p.m., e.s.t. on January 17, 2019; for the fourth quarter 2018 by 11:59 p.m., e.d.t. on April 18, 2019; and for the first quarter 2019 by 11:59 p.m., e.d.t. on July 18, 2019. These deadlines are firm; no exceptions will be permitted.

For more details about the CY 2020 HH QRP, we refer readers to 81 FR 76789.

5. HHCAHPS Requirements for the CY 2021 HH QRP

For the CY 2021 HH QRP, we propose to require the continued monthly HHCAHPS data collection and reporting for four quarters. The data collection period for the CY 2021 HH QRP includes the second quarter 2019 through the first quarter 2020 (the months of April 2019 through March 2020). HHAs will be required to submit their HHCAHPS data files to the HHCAHPS Data Center for the second quarter 2019 by 11:59 p.m., e.d.t. on October 17, 2019; for the third quarter 2019 by 11:59 p.m., e.s.t. on January 16, 2020; for the fourth quarter 2019 by 11:59 p.m., e.d.t. on April 16, 2020; and for the first quarter 2020 by 11:59 p.m., e.d.t. on July 16, 2020. These deadlines are firm; no exceptions will be permitted.

For the CY 2021 HH QRP, we propose to require that all HHAs with fewer than 60 HHCAHPS-eligible unduplicated or unique patients in the period of April 1, 2018 through March 31, 2019 are exempt from the HHCAHPS data collection and submission requirements for the CY 2021 HH QRP, upon completion of the CY 2021 HHCAHPS Participation Exemption Request form, and upon CMS verification of the HHA patient counts. Agencies with fewer

than 60 HHCAHPS-eligible, unduplicated or unique patients in the period of April 1, 2018 through March 31, 2019 are proposed to be required to submit their patient counts on the CY 2021 HHCAHPS Participation Exemption Request form posted on <https://homehealthcahps.org> from April 1, 2019 to 11:59 p.m., e.d.t. to March 31, 2020. This deadline is firm, as are all of the quarterly data submission deadlines for the HHAs that participate in HHCAHPS.

We propose to automatically exempt HHAs receiving Medicare certification on or after the start of the period in which HHAs do their patient count for a particular year's HHCAHPS data submission from the HHCAHPS reporting requirement for the year. We propose that HHAs receiving Medicare certification on or after April 1, 2019 would be exempt from the HHCAHPS reporting requirement for the CY 2021 HH QRP. As we have finalized in previous years, we propose that these newly-certified HHAs do not need to complete the HHCAHPS Participation Exemption Request Form for the CY 2021 HH QRP.

6. HHCAHPS Reconsiderations and Appeals Process

As finalized in previous rules, we propose that HHAs should monitor their respective HHCAHPS survey vendors to ensure that vendors submit their HHCAHPS data on time, by accessing their HHCAHPS Data Submission Reports on <https://homehealthcahps.org>. This helps HHAs ensure that their data are submitted in the proper format for data processing to the HHCAHPS Data Center.

We propose to continue HHCAHPS oversight activities as finalized in the previous rules. In the CY 2013 HH PPS final rule (77 FR 67068, 67164), we codified the current guideline that all approved HHCAHPS survey vendors must fully comply with all HHCAHPS oversight activities. We included this survey requirement at § 484.250(c)(3).

For further information on the HH QRP reconsiderations and appeals process, please see Section V.J.3. of this proposed rule.

7. Summary

We are not proposing any changes to the participation requirements, or to the requirements pertaining to the implementation of the Home Health CAHPS® Survey (HHCAHPS). We only updated the information to reflect the dates for future HH QRP years. We again strongly encourage HHAs to keep up-to-date about the HHCAHPS by regularly viewing the official Web site for the

HHCAHPS at <https://homehealthcahps.org>. HHAs can also send an email to the HHCAHPS Survey Coordination Team at hhaahps@rti.org or to CMS at homehealthcahps@cms.hhs.gov, or telephone toll-free (1-866-354-0985) for more information about the HHCAHPS Survey.

VI. Request for Information on CMS Flexibilities and Efficiencies

CMS is committed to transforming the health care delivery system—and the Medicare program—by putting an additional focus on patient-centered care and working with providers, physicians, and patients to improve outcomes. We seek to reduce burdens for hospitals, physicians, and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. These are the reasons we are including this Request for Information in this proposed rule.

As we work to maintain flexibility and efficiency throughout the Medicare program, we would like to start a national conversation about improvements that can be made to the health care delivery system that reduce unnecessary burdens for clinicians, other providers, and patients and their families. We aim to increase quality of care, lower costs improve program integrity, and make the health care system more effective, simple and accessible.

We would like to take this opportunity to invite the public to submit their ideas for regulatory, subregulatory, policy, practice, and procedural changes to better accomplish these goals. Ideas could include payment system redesign, elimination or streamlining of reporting, monitoring and documentation requirements, aligning Medicare requirements and processes with those from Medicaid and other payers, operational flexibility, feedback mechanisms and data sharing that would enhance patient care, support of the physician-patient relationship in care delivery, and facilitation of individual preferences. Responses to this Request for Information could also include recommendations regarding when and how CMS issues regulations and policies and how CMS can simplify rules and policies for beneficiaries, clinicians, physicians, providers, and suppliers. Where practicable, data and specific examples would be helpful. If the proposals involve novel legal questions, analysis regarding CMS' authority is welcome for CMS' consideration. We are particularly

interested in ideas for incentivizing organizations and the full range of relevant professionals and paraprofessionals to provide screening, assessment and evidence-based treatment for individuals with opioid use disorder and other substance use disorders, including reimbursement methodologies, care coordination, systems and services integration, use of paraprofessionals including community paramedics and other strategies. We are requesting commenters to provide clear and concise proposals that include data and specific examples that could be implemented within the law.

We note that this is a Request for Information only. Respondents are encouraged to provide complete but concise responses. This Request for Information is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This Request for Information does not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through this Request for Information and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this Request for Information; all costs associated with responding to this Request for Information will be solely at the interested party's expense. We note that not responding to this Request for Information does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this Request for Information announcement for additional information pertaining to this request. In addition, we note that CMS will not respond to questions about the policy issues raised in this Request for Information. CMS will not respond to comment submissions in response to this Request for Information in the FY 2018 HH PPS final rule. Rather, CMS will actively consider all input as we develop future regulatory proposals or future subregulatory policy guidance. CMS may or may not choose to contact individual responders. Such communications would be for the sole purpose of clarifying statements in the responders' written responses. Contractor support personnel may be used to review responses to this Request for Information. Responses to this notice are not offers and cannot be accepted by the Government to form a binding contract or issue a grant. Information obtained as a result of this Request for

Information may be used by the Government for program planning on a nonattribution basis. Respondents should not include any information that might be considered proprietary or confidential. This Request for Information should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. CMS may publically post the public comments received, or a summary of those public comments.

VII. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the OMB for review and approval. We note that we will submit a revised information collection request (OMB control number 0938-1279) to OMB for review. This will also extend the information collection request which expires December 30, 2019. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

This proposed rule makes reference to associated information collections that are not discussed in the regulation text contained in this document.

B. Collection of Information Requirements for the HH QRP

We believe that the burden associated with the HH QRP is the time and effort associated with data collection and reporting. As of April 1, 2017, there are approximately 12,149 HHAs currently reporting quality data to CMS. For the purposes of calculating the costs associated with the collection of information requirements, we obtained mean hourly wages for these staff from the U.S. Bureau of Labor Statistics' May 2016 National Occupational

Employment and Wage Estimates
(http://www.bls.gov/oes/current/oes_

nat.htm). To account for overhead and fringe benefits (100 percent), we have

doubled the hourly wage. These amounts are detailed in Table 52.

TABLE 52—U.S. BUREAU OF LABOR STATISTICS' MAY 2016 NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage (\$/hr)	Fringe benefit (100%) (\$/hr)	Adjusted hourly wage (\$/hr)
Registered Nurse (RN)	29-1141	\$34.70	\$34.70	\$69.40
Physical therapists HHAs	29-1123	46.42	46.42	92.84
Speech-Language Pathologists (SLP)	29-1127	37.60	37.60	75.20
Occupational Therapists (OT)	29-1122	40.25	40.25	80.50

The OASIS changes proposed in section V.D of this proposed rule will result in the removal of 75 data elements from the OASIS at the time point of Start of Care (SOC), 75 data elements at the time point of Resumption of Care (ROC), 20 data elements at the time point of Follow-up (FU), 42 data elements at the time point of Transfer to an Inpatient Facility (TOC), 1 data element at the time point of Death at Home (Death), and 34 data elements at the time point of Discharge from Agency (Discharge). These data items will not be used in the calculation of quality measures adopted in the HH QRP nor are they used for previously established purposes that are non-related to our HH QRP. More detail on these OASIS data elements proposed for removal can be found at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/OASIS-Data-Sets.html>.

Section V.F.1 of this rule proposes to adopt a new pressure ulcer measure to replace the current pressure ulcer measure that has been specified under section 1899B(c)(1)(B) of the Act beginning with the CY 2020 HH QRP. The proposed replacement measure is entitled, "Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury." The new measure will be calculated using data elements that are currently collected and reported using the OASIS-C2 (version effective January 1, 2017). Adoption of the Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury measure would result in the removal of item M1313, related to pressure ulcer assessment that we believe is duplicative and no longer necessary. Specifically, with adoption of Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury measure, we would remove 6 data elements at Discharge.

In sections V.F.2 of this proposed rule, we are proposing a new quality measure to meet requirements of the

IMPACT Act under section 1899B(c)(1)(A) of the Act beginning with the CY 2020 HH QRP titled "Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631)." Specifically, we are proposing to add 13 standardized patient assessment data elements at SOC, 13 data elements at ROC, 15 standardized patient assessment data elements at FU, and 13 standardized patient assessment data elements at Discharge.

In sections V.F.3 of this proposed rule, we are proposing a new quality measure to meet requirements of the IMPACT Act under section 1899B(c)(1)(D) of the Act beginning with the CY 2020 HH QRP titled "Application of Percent of Residents Experiencing One or More Falls with Major Injury (NQF# 0674)." The new measure will be calculated using new standardized data elements added to the OASIS. Specifically, we are proposing to add 4 data elements at TOC, 4 data elements at Death, and 4 data elements at Discharge.

In sections V.H.2 and V.H.3 of this proposed rule, we are proposing requirements related to the reporting of standardized patient assessment data beginning with the CY 2019 HH QRP. We are proposing to define the term "standardized patient assessment data" as patient assessment questions and response options that are identical in all four PAC assessment instruments, and to which identical standards and definitions apply. The standardized patient assessment data is intended to be shared electronically among PAC providers and will otherwise enable the data to be comparable for various purposes, including the development of cross-setting quality measures and to inform payment models that take into account patient characteristics rather than setting. Specifically, we are proposing to add 53 standardized

patient assessment data elements at SOC, 53 standardized patient assessment data elements at ROC, and 36 standardized patient assessment data elements at Discharge.

The OASIS instrument is used for both the HH QRP and the HH PPS. As outlined in section III.E of this proposed rule, to calculate the case-mix adjusted payment amount (specifically the functional level assignment), we are proposing to add collection of two current OASIS-C2 items (10 data elements) at the FU time point:

- M1033: Risk for Hospitalization (9 data elements)
- M1800: Grooming (1 data element).

As outlined in section III.E of this proposed rule, OASIS integumentary status items would not be needed in case-mix adjusting the period payment; therefore, we are proposing to remove collection of eight current OASIS-C2 items (19 data elements) at the FU time point:

- M1311: Current Number of Unhealed Pressure Ulcers at Each Stage (12 data elements)
- M1322: Current Number of Stage 1 Pressure Ulcers (1 data element)
- M1324: Stage of Most Problematic Unhealed Pressure Ulcer that is Stageable (1 data element)
- M1330: Does this patient have a Stasis Ulcer? (1 data element)
- M1332: Current Number of Stasis Ulcer(s) that are Observable (1 data element)
- M1334: Status of Most Problematic Stasis Ulcer that is Observable (1 data element)
- M1340: Does this patient have a Surgical Wound? (1 data element)
- M1342: Status of Most Problematic Surgical Wound that is Observable (1 data element).

Therefore, we are proposing the net removal associated with the HHGM of 9 data elements at FU.

In summary, there is a net reduction of 9 data elements at SOC, 9 data elements at ROC, 14 data elements at FU

and 38 data elements at TOC. There is a net increase of 3 data elements at Death and 13 data elements at Discharge.

Under section 1899B(m) of the Act, the Paperwork Reduction Act does not apply to section 1899B, or to the sections of the OASIS that require modification to achieve the standardization of patient assessment data. We are, however, setting out the burden as a courtesy to advise interested parties of the proposed actions' time and costs and for reference in the regulatory impact analysis (RIA) section IX. The requirement and burden will be submitted to OMB for review and

approval when the modifications to the OASIS have achieved standardization and are no longer exempt from the requirements under section 1899B(m) of the Act.

We assume that each data element requires 0.3 minutes of clinician time to complete. Therefore, there is a reduction in clinician burden per OASIS assessment of 2.7 minutes at SOC, 2.7 minutes at ROC, 4.2 minutes at FU and 11.4 minutes at TOC. There is an increase in clinician burden per assessment of 0.9 minutes at Death and 3.9 minutes at Discharge.

The OASIS is completed by RNs or PTs, or very occasionally by occupational therapists (OT) or speech

language pathologists (SLP/ST). Data from 2016 show that the SOC/ROC OASIS is completed by RNs (approximately 87 percent of the time), PTs (approximately 12.7 percent of the time), and other therapists, including OTs and SLP/STs (approximately 0.3 percent of the time). Based on this analysis we estimated a weighted clinician average hourly wage of \$72.40, inclusive of fringe benefits, using the hourly wage data in Table 52. Individual providers determine the staffing resources necessary.

Table 53 shows the total number of assessments submitted in CY 2016 and estimated burden at each time point.

TABLE 53—CY 2016 OASIS SUBMISSIONS AND ESTIMATED BURDEN, BY TIME POINT

Time point	CY 2016 assessments completed	Estimated burden (\$)
Start of Care	6,261,934	— \$20,401,380.97
Resumption of Care	1,049,247	— 3,418,446.73
Follow-up	3,797,410	— 19,245,273.88
Transfer to an inpatient facility	1,892,099	— 26,027,713.84
Death at Home	41,128	44,665.01
Discharge from agency	5,120,124	24,095,303.54
Total	18,161,942	— 44,952,846.87

* Estimated Burden (\$) at each Time-Point = (# CY 2016 Assessments Completed) × (clinician burden [min]/60) × (\$72.40 [weighted clinician average hourly wage]).

Based on the data in Table 53, for the 12,149 active Medicare-certified HHAs in April 2017, we estimate the total average decrease in cost associated with proposed changes to the HH QRP at \$3,700.74 per HHA annually, or \$44,952,846.87 for all HHAs annually. This decrease in burden will be accounted for in the information collection under OMB control number 0938–1279.

C. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection and recordkeeping requirements. The requirements are not effective until they have been approved by OMB.

We invite public comments on these information collection requirements. If you wish to comment, please identify the rule (CMS–1672–P) and, where applicable, the ICR's CFR citation, CMS ID number, and OMB control number.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <https://www.cms.gov/Regulations-and->

Guidance/Legislation/Paperwork Reduction Act of 1995/PRA-Listing.html.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786–1326.

See this rule's **DATES** and **ADDRESSES** sections for the comment due date and for additional instructions.

VIII. Response to Public Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IX. Regulatory Impact Analysis

A. Statement of Need

Section 1895(b)(1) of the Act requires the Secretary to establish a HH PPS for all costs of HH services paid under Medicare. In addition, section 1895(b) of the Act requires: (1) The computation of a standard prospective payment amount

include all costs for HH services covered and paid for on a reasonable cost basis and that such amounts be initially based on the most recent audited cost report data available to the Secretary; (2) the prospective payment amount under the HH PPS to be an appropriate unit of service based on the number, type, and duration of visits provided within that unit; and (3) the standardized prospective payment amount be adjusted to account for the effects of case-mix and wage levels among HHAs. Section 1895(b)(3)(B) of the Act addresses the annual update to the standard prospective payment amounts by the HH applicable percentage increase. Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act require the standard prospective payment amount to be adjusted for case-mix and geographic differences in wage levels. Section 1895(b)(4)(B) of the Act requires the establishment of appropriate case-mix adjustment factors for significant variation in costs among different units of services. Lastly, section 1895(b)(4)(C) of the Act requires the establishment of wage adjustment factors that reflect the relative level of wages, and wage-related costs applicable to HH services

furnished in a geographic area compared to the applicable national average level.

Section 1895(b)(3)(B)(iv) of the Act provides the Secretary with the authority to implement adjustments to the standard prospective payment amount (or amounts) for subsequent years to eliminate the effect of changes in aggregate payments during a previous year or years that was the result of changes in the coding or classification of different units of services that do not reflect real changes in case-mix. Section 1895(b)(5) of the Act provides the Secretary with the option to make changes to the payment amount otherwise paid in the case of outliers because of unusual variations in the type or amount of medically necessary care. Section 1895(b)(3)(B)(v) of the Act requires HHAs to submit data for purposes of measuring health care quality, and links the quality data submission to the annual applicable percentage increase.

The HHVBP Model will apply a payment adjustment based on an HHA's performance on quality measures to test the effects on quality and costs of care.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA, March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2) and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity).

Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) Having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or

communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). The net transfer impact related to the changes in payments under the HH PPS for CY 2018 is estimated to be –\$80 million (–0.4 percent). The net transfer impact in CY 2019 related to the change in the unit of payment under the proposed HHGM is estimated to be –\$950 million (–4.3 percent) if the HHGM is implemented in a fully non-budget neutral manner in CY 2019. The net transfer impact in CY 2019 related to the change in the unit of payment under the proposed HHGM is estimated to be –\$480 million (–2.2 percent) if the HHGM is implemented in a partially budget-neutral manner in CY 2019 with the removal of the HHGM partial budget neutrality adjustment factor in CY 2020. The savings impacts related to the HHVBP model as a whole are estimated at a total projected 5-year gross savings of \$378 million assuming a savings estimate of a 6 percent annual reduction in hospitalizations and a 1.0 percent annual reduction in SNF admissions; the portion attributable to this proposed rule is negligible. In the CY 2018 HH PPS proposed rule, we have identified a reduction in our regulatory reporting burden of \$44,952,846.87. We estimate that this rulemaking is “economically significant” as measured by the \$100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis that, to the best of our ability, presents the costs and benefits of the rulemaking.

In addition, section 1102(b) of the Act requires us to prepare a RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This proposed rule is applicable exclusively to HHAs. Therefore, the Secretary has determined this rule would not have a

significant economic impact on the operations of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2017, that threshold is approximately \$148 million. This proposed rule is not anticipated to have an effect on State, local, or tribal governments, in the aggregate, or on the private sector of \$148 million or more.

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities that will review this proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is \$105.16 per hour, including overhead and fringe benefits (https://www.bls.gov/oes/2016/may/naics4_621100.htm). Assuming an average reading speed, we estimate that it would take approximately 3.8 hours for the staff to review half of this proposed rule. For each HHA that reviews the rule, the estimated cost is \$399.61 (3.8 hours × \$105.16). Therefore, we estimate that the total cost of reviewing this regulation is \$33,966.85 (\$399.61 × 85 reviewers).

1. HH PPS for CY 2018

The update set forth in this rule applies to Medicare payments under HH PPS in CY 2018. Accordingly, the following analysis describes the impact in CY 2018 only. We estimate that the net impact of the policies in this rule is approximately \$80 million in decreased payments to HHAs in CY 2018. We applied a wage index budget neutrality factor and a case-mix weights budget neutrality factor to the rates as discussed in section III.C.3 of this proposed rule. Therefore, the estimated impact of the 2018 wage index and the recalibration of the case-mix weights for 2018 is zero. The –\$80 million impact reflects the distributional effects of a 0.5 percent reduction in payments due to the sunset of the rural add-on provision (\$100 million decrease), a 1 percent home health payment update percentage (\$190 million increase), and a –0.97 percent adjustment to the national, standardized 60-day episode payment rate to account for nominal case-mix growth for an impact of –0.9 percent (\$170 million decrease). The \$80 million in decreased payments is reflected in the last column of the first row in Table 54 as a 0.4 percent decrease in expenditures when comparing CY 2017 payments to estimated CY 2018 payments.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than \$7.5 million to \$38.5 million in any one year. For the purposes of the RFA, we estimate that almost all HHAs are small entities as that term is used in the RFA. Individuals and states are not included in the definition of a small entity. The economic impact assessment is based on estimated Medicare payments (revenues) and HHS's practice in interpreting the RFA is to consider effects economically "significant" only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. The majority of HHAs' visits are Medicare-paid visits and therefore the majority of HHAs' revenue consists of Medicare payments. Based on our analysis, we conclude that the policies proposed in this rule would result in an estimated total impact of 3 to 5 percent or more on Medicare revenue for greater than 5

percent of HHAs. Therefore, the Secretary has determined that this HH PPS proposed rule would have a significant economic impact on a substantial number of small entities. Further detail is presented in Table 54, by HHA type and location.

With regards to options for regulatory relief, the sunset of rural add-on payments for CY 2018 is statutory and we do not have the authority to authorize rural add-on payments past December 31, 2017. We believe it is appropriate to reduce the national, standardized 60-day episode payment amount by 0.97 percent in CY 2018 to account for the estimated increase in nominal case-mix in order to move towards more accurate payment for the delivery of home health services where payments better align with the costs of providing such services.

2. HH PPS for CY 2019 (Proposed HHGM)

The net transfer impacts in CY 2019 related to the proposed change in the unit of payment under the HHGM are estimated to be –\$950 million (–4.3 percent) if implemented in a fully non-budget neutral manner in CY 2019. The net transfer impact in CY 2019 related to the change in the unit of payment under the proposed HHGM is estimated to be –\$480 million (–2.2 percent) if the HHGM is implemented in a partially budget-neutral manner in CY 2019 with the removal of the HHGM partial budget neutrality adjustment factor in CY 2020. Based on our analysis, we conclude that the implementation of the HHGM in CY 2019 would result in an estimated total impact of 3 to 5 percent or more on Medicare revenue for greater than 5 percent of HHAs, and therefore, would have a significant economic impact on a substantial number of small entities. Further detail is presented in Table 55, by HHA type and location.

With regards to options for regulatory relief, changing the unit of payment from a 60-day episode to a 30-day period is not subject to the budget neutrality requirements under section 1895 of the Act and would result in an estimated 4.3 percent decrease (–\$950 million) in total HH PPS payments in CY 2019. As outlined in section III.E.3, we are proposing to implement the change in the unit of payment from 60-day episodes of care to 30-day periods care in a non-budget neutral manner as doing so would better align home health payments with the costs of providing care. However, as noted in section III.E.3, we are considering potential alternative implementation approaches for the HHGM, including, but not limited to, a partially budget-neutral

approach with a phase-out period. Specifically, we are considering applying a HHGM partial budget neutrality adjustment factor that would reduce the estimated impact of the HHGM from an estimated –4.3 percent to –2.2 percent in CY 2019, to be eliminated as soon as CY 2020. We invite comments on whether to implement the HHGM in a fully non-budget neutral manner beginning in CY 2019, as proposed; whether to implement the HHGM in CY 2019 with a HHGM partial budget neutrality adjustment factor applied and then subsequently removed in CY 2020; or whether a HHGM partial budget neutrality adjustment factor should be applied and then phased-out over a longer period of time.

HHAs that provide a larger percentage of overall visits as therapy visits compared to skilled nursing visits may experience larger decreases in payments under the HHGM. We do not believe it would be appropriate to offer regulatory relief, or otherwise mitigate the impact of the proposed HHGM, for HHAs that provide a preponderance of their visits as therapy visits compared to nursing visits. The HHGM would still provide adequate reimbursement for therapy services and was developed, in part, to eliminate the current therapy thresholds that encourage the provision of the most profitable number of therapy visits, even when patient need may not justify such services. We anticipate that HHAs currently providing excess therapy visits solely to maximize reimbursement, as outlined in section II.D of this proposed rule, will no longer do so under the HHGM. We note that therapy continues to be a valued home health service, as two of the six clinical groups (neuro/stroke rehabilitation and musculoskeletal rehabilitation) under the HHGM reflect instances where therapy would be the primary focus of home health care.

3. HHVBP Model

Under the HHVBP Model, the first payment adjustment will apply in CY 2018 based on PY1 (2016) data and the final payment adjustment will apply in CY 2022 based on PY5 (2020) data. In the CY 2016 HH PPS final rule, we estimated that the overall impact of HHVBP Model from CY 2018 through CY 2022 was a reduction of approximately \$380 million (80 FR 68716). In the CY 2017 HH PPS final rule, we estimated that the overall impact of the HHVBP Model from CY 2018 through CY 2022 was a reduction of approximately \$378 million (81 FR 76795). We do not believe the proposed

changes in this rule would affect the prior estimates.

C. Detailed Economic Analysis

This rule proposes updates for CY 2018 to the HH PPS rates contained in the CY 2017 HH PPS final rule (81 FR 76702 through 76797). The impact analysis of this proposed rule presents the estimated expenditure effects of policy changes proposed in this rule. We use the latest data and best analysis available, but we do not make adjustments for future changes in such variables as number of visits or case-mix.

This analysis incorporates the latest estimates of growth in service use and payments under the Medicare HH benefit, based primarily on Medicare claims data from 2016. We note that certain events may combine to limit the scope or accuracy of our impact analysis, because such an analysis is future-oriented and, thus, susceptible to errors resulting from other changes in the impact time period assessed. Some examples of such possible events are newly-legislated general Medicare program funding changes made by the Congress, or changes specifically related to HHAs. In addition, changes to the Medicare program may continue to be made as a result of the Affordable Care

Act, or new statutory provisions. Although these changes may not be specific to the HH PPS, the nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon HHAs.

1. HH PPS for CY 2018

Table 54 represents how HHA revenues are likely to be affected by the policy changes proposed in this rule for CY 2018. For this analysis, we used an analytic file with linked CY 2016 OASIS assessments and HH claims data for dates of service that ended on or before December 31, 2016. The first column of Table 54 classifies HHAs according to a number of characteristics including provider type, geographic region, and urban and rural locations. The second column shows the number of facilities in the impact analysis. The third column shows the payment effects of the CY 2018 wage index. The fourth column shows the payment effects of the CY 2018 case-mix weights. The fifth column shows the effects the 0.97 percent reduction to the national, standardized 60-day episode payment amount to account for nominal case-mix growth. The sixth column shows the

payment effects from the sunset of the rural add-on payment provision in statute. The seventh column shows the effects of the CY 2018 home health payment update percentage.

The last column shows the combined effects of all the policies proposed in this rule. Overall, it is projected that aggregate payments in CY 2018 would decrease by 0.4 percent. As illustrated in Table 54, the combined effects of all of the changes vary by specific types of providers and by location. We note that some individual HHAs within the same group may experience different impacts on payments than others due to the distributional impact of the CY 2018 wage index, the extent to which HHAs had episodes in case-mix groups where the case-mix weight decreased for CY 2018 relative to CY 2017, the percentage of total HH PPS payments that were subject to the low-utilization payment adjustment (LUPA) or paid as outlier payments, and the degree of Medicare utilization. In addition, we clarify that there are negative estimated impacts attributed to the sunset of the rural add-on provision for HHAs located in urban areas as well as rural areas. This is due to the fact that HHAs located in urban areas provide services to patients located in rural areas and payments are based on the location of the beneficiary.

TABLE 54—ESTIMATED HHA IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY, CY 2018

	Number of agencies	CY 2018 wage index ¹ (%)	CY 2018 case-mix weights ² (%)	60-day episode rate nominal case-mix reduction ³ (%)	Sunset of rural add-on (%)	HH payment update percentage ⁴ (%)	Total (%)
All Agencies	10,930	0.0	0.0	−0.9	−0.5	1.0	−0.4
Facility Type and Control							
Free-Standing/Other Vol/NP	1,089	0.0	0.1	−0.8	−0.4	1.0	−0.1
Free-Standing/Other Proprietary	8,588	0.0	0.0	−0.9	−0.4	1.0	−0.3
Free-Standing/Other Government	322	−0.2	0.2	−0.9	−1.4	1.0	−1.3
Facility-Based Vol/NP	646	0.0	0.3	−0.8	−0.7	1.0	−0.2
Facility-Based Proprietary	92	−0.2	0.2	−0.9	−1.3	1.0	−1.2
Facility-Based Government	193	−0.2	0.2	−0.9	−1.4	1.0	−1.3
Subtotal: Freestanding	9,999	0.0	0.0	−0.9	−0.4	1.0	−0.3
Subtotal: Facility-based	931	−0.1	0.3	−0.8	−0.8	1.0	−0.4
Subtotal: Vol/NP	1,735	0.0	0.2	−0.8	−0.5	1.0	−0.1
Subtotal: Proprietary	8,680	0.0	0.0	−0.9	−0.5	1.0	−0.4
Subtotal: Government	515	−0.2	0.2	−0.9	−1.4	1.0	−1.3
Facility Type and Control: Rural							
Free-Standing/Other Vol/NP	267	0.2	0.2	−0.9	−2.5	1.0	−2.0
Free-Standing/Other Proprietary	814	−0.2	−0.1	−0.9	−2.3	1.0	−2.5
Free-Standing/Other Government	229	−0.4	0.1	−0.9	−2.6	1.0	−2.8
Facility-Based Vol/NP	291	−0.4	0.2	−0.9	−2.7	1.0	−2.8
Facility-Based Proprietary	47	−0.1	0.2	−0.9	−2.7	1.0	−2.5
Facility-Based Government	142	−0.2	0.2	−0.9	−2.6	1.0	−2.5
Facility Type and Control: Urban							
Free-Standing/Other Vol/NP	822	−1.0	0.1	−0.8	−0.1	1.0	−0.8

TABLE 54—ESTIMATED HHA IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY, CY 2018—Continued

	Number of agencies	CY 2018 wage index ¹ (%)	CY 2018 case-mix weights ² (%)	60-day episode rate nominal case-mix reduction ³ (%)	Sunset of rural add-on (%)	HH payment update percentage ⁴ (%)	Total (%)
Free-Standing/Other Proprietary	7,774	0.0	0.0	−0.9	−0.2	1.0	−0.1
Free-Standing/Other Government	93	0.0	0.2	−0.9	−0.1	1.0	0.2
Facility-Based Vol/NP	355	0.1	0.3	−0.8	−0.1	1.0	0.5
Facility-Based Proprietary	45	−0.3	0.2	−0.9	−0.2	1.0	−0.2
Facility-Based Government	51	−0.2	0.3	−0.9	−0.3	1.0	−0.1
Facility Location: Urban or Rural							
Rural	1,790	−0.1	0.0	−0.9	−2.4	1.0	−2.4
Urban	9,140	0.0	0.0	−0.9	−0.2	1.0	−0.1
Location: Region of the Country (Census Region)							
New England	346	0.1	0.1	−0.8	−0.3	1.0	0.1
Mid Atlantic	488	0.0	0.0	−0.8	−0.2	1.0	0.0
East North Central	2,216	0.0	0.2	−0.9	−0.4	1.0	−0.1
West North Central	706	0.3	0.2	−0.9	−0.8	1.0	−0.2
South Atlantic	1,721	−0.1	−0.1	−0.9	−0.3	1.0	−0.4
East South Central	423	−0.2	−0.2	−0.9	−1.3	1.0	−1.6
West South Central	2,972	0.2	−0.2	−0.9	−0.7	1.0	−0.6
Mountain	668	−0.3	0.1	−0.9	−0.4	1.0	−0.5
Pacific	1,343	0.1	0.5	−0.9	−0.1	1.0	0.6
Other	47	0.2	−1.0	−0.8	−0.6	1.0	−1.2
Facility Size (Number of 1st Episodes)							
<100 episodes	3,109	0.1	0.2	−0.9	−0.4	1.0	0.0
100 to 249	2,478	0.1	0.2	−0.9	−0.5	1.0	−0.1
250 to 499	2,203	0.1	0.2	−0.9	−0.5	1.0	−0.1
500 to 999	1,646	0.0	0.1	−0.9	−0.5	1.0	−0.3
1,000 or More	1,494	0.0	−0.1	−0.9	−0.5	1.0	−0.5

Source: CY 2016 Medicare claims data for episodes ending on or before December 31, 2016 for which we had a linked OASIS assessment.

¹ The impact of the CY 2018 home health wage index is offset by the wage index budget neutrality factor described in section III.C.3 of this proposed rule.

² The impact of the CY 2018 home health case-mix weights reflects the recalibration of the case-mix weights offset by the case-mix weights budget neutrality factor described in section III.B of this proposed rule.

³ The 0.97 percent reduction to the national, standardized 60-day episode payment amount in CY 2018 is estimated to have a 0.9 percent impact on overall HH PPS expenditures.

⁴ The CY 2018 home health payment update percentage reflects the home health payment update of 1 percent as described in section III.C.1 of this proposed rule.

Region Key:

New England = Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont; *Middle Atlantic* = Pennsylvania, New Jersey, New York; *South Atlantic* = Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia; *East North Central* = Illinois, Indiana, Michigan, Ohio, Wisconsin; *East South Central* = Alabama, Kentucky, Mississippi, Tennessee; *West North Central* = Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota; *West South Central* = Arkansas, Louisiana, Oklahoma, Texas; *Mountain* = Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming; *Pacific* = Alaska, California, Hawaii, Oregon, Washington; *Other* = Guam, Puerto Rico, Virgin Islands.

2. HH PPS for CY 2019 (Proposed HHGM)

Table 55 represents how HHA revenues are likely to be affected by the policy changes proposed in this rule for CY 2019. For this analysis, we used an analytic file with linked CY 2016 OASIS assessments and CY 2016 HH claims data (as of March 17, 2017) for dates of service that ended on or before December 31, 2016. The first column of Table 55 classifies HHAs according to a number of characteristics including provider type, geographic region, and urban and rural locations. The second

column shows the number of facilities in the impact analysis. The third and fourth columns shows the impact of the proposed HHGM as outlined in section III.E of this proposed rule. Overall, before application of the home health payment update percentage for CY 2019, it is projected that aggregate payments in CY 2019 would decrease by \$950 million (−4.3 percent) if implemented in a fully non-budget neutral manner and by −\$480 million (−2.2 percent) if the HHGM is implemented in a partially budget-neutral manner in CY 2019 with the removal of the HHGM partial budget neutrality adjustment factor in CY 2020.

As illustrated in Table 55, the effect of the proposed HHGM varies by specific types of providers and by location. We note that some individual HHAs within the same group may experience different impacts on payments than others. This is due to distributional differences among HHAs with regards to the percentage of total HH PPS payments that were subject to the low-utilization payment adjustment (LUPA) or paid as outlier payments, the degree of Medicare utilization, and the ratio of overall visits that were provided as therapy versus skilled nursing.

TABLE 55—ESTIMATED HHA IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY, CY 2019

	Number of agencies	Implementa- tion of the HHGM (not budget neutral) (%)	Implementa- tion of the HHGM (partially bud- get neutral) (%)
All Agencies	10,860	-4.3	-2.2
Facility Type and Control			
Free-Standing/Other Vol/NP	1,085	-1.3	0.9
Free-Standing/Other Proprietary	8,525	-5.7	-3.6
Free-Standing/Other Government	319	-2.9	-0.7
Facility-Based Vol/NP	646	-0.2	2.0
Facility-Based Proprietary	92	0.4	2.6
Facility-Based Government	193	1.3	3.6
Subtotal: Freestanding	9,929	-4.7	-2.6
Subtotal: Facility-based	931	0.0	2.2
Subtotal: Vol/NP	1,731	-1.0	1.2
Subtotal: Proprietary	8,617	-5.7	-3.6
Subtotal: Government	512	-0.7	1.5
Facility Type and Control: Rural			
Free-Standing/Other Vol/NP	267	0.2	2.5
Free-Standing/Other Proprietary	808	-0.6	1.7
Free-Standing/Other Government	226	-1.7	0.6
Facility-Based Vol/NP	291	0.3	2.5
Facility-Based Proprietary	47	5.0	7.3
Facility-Based Government	142	1.8	4.1
Facility Type and Control: Urban			
Free-Standing/Other Vol/NP	818	-1.5	0.7
Free-Standing/Other Proprietary	7,717	-6.3	-4.3
Free-Standing/Other Government	93	-4.2	-2.0
Facility-Based Vol/NP	355	-0.3	1.9
Facility-Based Proprietary	45	-3.1	-1.0
Facility-Based Government	51	0.9	3.1
Facility Location: Urban or Rural			
Rural	1,781	-0.2	2.1
Urban	9,079	-4.9	-2.8
Facility Location: Region of the Country (Census Region)			
New England	339	-2.3	-0.2
Mid Atlantic	485	-0.6	1.5
East North Central	2,199	-5.2	-3.1
West North Central	705	-7.9	-5.9
South Atlantic	1,713	-10.2	-8.2
East South Central	423	-3.2	-1.0
West South Central	2,947	-0.3	1.9
Mountain	662	-9.7	-7.8
Pacific	1,340	0.1	2.3
Other	47	6.0	8.4
Facility Size (Number of 1st Episodes)			
< 100 episodes	3,040	-2.9	-0.8
100 to 249	2,478	-3.8	-1.7
250 to 499	2,203	-3.9	-1.8
500 to 999	1,645	-4.6	-2.5
1,000 or More	1,494	-4.4	-2.3
Nursing/Therapy Visits Ratio			
1st Quartile (Lowest 25 Nursing)	2,715	-14.4	-12.6
2nd Quartile	2,715	-4.6	-2.5
3rd Quartile	2,715	2.6	4.9

TABLE 55—ESTIMATED HHA IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY, CY 2019—Continued

	Number of agencies	Implementa- tion of the HHGM (not budget neutral) (%)	Implementa- tion of the HHGM (partially budg- et neutral) (%)
4th Quartile (Top 25 Nursing)	2,715	12.9	15.5

Source: CY 2016 Medicare claims data (as of March 17, 2017) for episodes ending on or before December 31, 2016 for which we had a linked OASIS assessment.

Notes: This analysis includes assumptions on behavioral responses as a result of the new case-mix adjustment methodology and omits 360,683 individuals not grouped under the HHGM (either due to a missing OASIS, because they could be assigned to a clinical grouping, or had missing therapy/nursing visits). After converting 60-day episodes to 30-day periods for the HHGM, a further 28 periods were excluded with missing wage index information, 17 periods with missing NRS weights, and 2,376 periods with a missing urban/rural indicator. These excluded episodes results overall in 70 fewer HHAs being represented than in Table 54.

Region Key:

New England = Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont; Middle Atlantic = Pennsylvania, New Jersey, New York; South Atlantic = Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia; East North Central = Illinois, Indiana, Michigan, Ohio, Wisconsin; East South Central = Alabama, Kentucky, Mississippi, Tennessee; West North Central = Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota; West South Central = Arkansas, Louisiana, Oklahoma, Texas; Mountain = Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming; Pacific = Alaska, California, Hawaii, Oregon, Washington; Other = Guam, Puerto Rico, Virgin Islands.

3. HHVBP Model

Table 57 displays our analysis of the distribution of possible payment adjustments at the 3-percent, 5-percent, 6-percent, 7-percent, and 8-percent rates that are being used in the Model using the 2015 and 2016 OASIS-based measures, claims-based hospitalization and Emergency Department (ED) measures, and HHCAHPS data. Full 2016 data are not yet available for claims-based and HHCAHPS-based measures. For these measures, we used the available data—12 months of episodes ending September 30, 2016 for claims-based measures and 12 months ending June 30, 2016 for HHCAHPS-based measures. The estimated impacts account for the minimum 40 HHCAHPS completed surveys proposal and the proposal to remove the OASIS-based measure, Drug Education on All Medications Provided to Patient/Caregiver during all Episodes of Care beginning in PY 3. We simulated the impacts based on nine (9) OASIS quality measures, two (2) claims-based measures in QIES, and the three (3) New Measures (using the October 2016 and January 2017 submission data), using the QIES Roll Up File data in the same manner as they will be in the Model. HHAs were classified as being in the smaller or larger volume cohort using the 2015 Quality Episode File, which is created using OASIS assessments. The basis of the payment adjustment was derived from complete 2015 claims data. We note that this impact analysis is based on the aggregate value of all nine (9) states.

Table 58 displays our analysis of the distribution of possible payment adjustments based on the same 2015–2016 data used to calculate Table 57, providing information on the estimated

impact of the proposals in this rule. We note that this impact analysis is based on the aggregate value across all nine (9) Model states. Note that all Medicare-certified HHAs that provide services in Massachusetts, Maryland, North Carolina, Florida, Washington, Arizona, Iowa, Nebraska, and Tennessee are required to compete in this Model. This analysis reflects that under our proposal, only HHAs that have data for at least five measures that meet the requirements of proposed § 484.305 would be included in the LEF and would have a payment adjustment calculated. Value-based incentive payment adjustments for the estimated 1,600 plus HHAs in the selected states that will compete in the HHVBP Model are stratified by size as described in section IV.B. of the CY 2017 HH PPS final rule. As finalized in section IV.B. of the CY 2017 final rule, there must be a minimum of eight (8) HHAs in any cohort.

Those HHAs that are in states that do not have at least eight smaller-volume HHAs will not have a separate smaller-volume cohort and thus there will only be one cohort that will include all the HHAs in that state. As indicated in Table 58, Maryland, North Carolina, Tennessee and Washington will only have one cohort while Arizona, Florida, Iowa, Massachusetts, and Nebraska will have both a smaller-volume cohort and a larger-volume cohort. For example, Iowa has 32 HHAs eligible to be exempt from being required to have their beneficiaries complete HHCAHPS surveys because they provided HHA services to less than 60 beneficiaries. Therefore, those 32 HHAs would be competing in Iowa's smaller-volume cohort for the 2016 performance year under the Model.

Using 2015–2016 data and the maximum payment adjustment for performance year 1 of 3-percent (as applied in CY 2018), based on the nine (9) OASIS quality measures, two (2) claims-based measures in QIES, the five (5) HHCAHPS measures, and the three (3) New Measures, the smaller-volume HHAs in Iowa would have a mean payment adjustment of 0.0 percent (Table 58). Only 10-percent of HHAs in the smaller-volume cohort would be subject to downward payment adjustments of more than minus 1.4 percent (–1.4 percent). The next columns provide the distribution of scores by percentile; we see that the cohort payment adjustment distribution for HHAs in Iowa in the smaller-volume cohort ranges from –1.4 percent at the 10th percentile to +1.3 percent at the 90th percentile, while the cohort payment adjustment distribution median is –0.2 percent.

Table 59 provides the payment adjustment distribution based on agency size, proportion of dually-eligible beneficiaries, average case mix (using the average case-mix for non-LUPA episodes), the proportion of the HHA's beneficiaries that reside in rural areas and HHA organizational status. HHAs with a higher proportion of dually-eligible beneficiaries and HHAs whose beneficiaries have higher acuity tend to have better performance.

The payment adjustment percentages were calculated at the state and size cohort level. Hence, the values of each separate analysis in the tables are representative of the baseline year of 2015 and the performance year of 2016 (though full 2016 data are not yet available for claims- and HHCAHPS-based measures). There were 1,674 HHAs in the nine selected states out of

1,894 HHAs that had a sufficient number of measures to receive a payment adjustment in the Model. It is expected that a certain number of HHAs will not have a payment adjustment because they may be servicing too small of a population to report on an adequate number of measures to calculate a TPS.

Additional analysis (see Table 60) was conducted to illustrate the effect of our proposal to require 40 or more

completed HHCAHPS surveys versus 20 or more completed HHCAHPS surveys. The percentage difference in the average TPS across all larger-volume HHAs for each state ranged from -0.4 percent through 2.2 percent and the majority of states were close to zero. We include information on average statewide TPS (by size cohort) because this is what is used to determine payment adjustment amounts in HHVBP. The relative

ranking of one HHA's TPS to the average TPS will directly affect the HHA's payment adjustment amount. The reporting of TPS also shows that this change has no impact on the TPS for the smaller volume cohort, for which the HHCAHPS measures are not used (regardless of the minimum sample size).

TABLE 57—ADJUSTMENT DISTRIBUTION BY PERCENTILE LEVEL OF QUALITY TOTAL PERFORMANCE SCORE AT DIFFERENT MODEL PAYMENT ADJUSTMENT RATES
[Percentage]

Payment adjustment distribution	Range (%)	10%	20%	30%	40%	Median (%)	60%	70%	80%	90%
3% Payment Adjustment For Performance Year 1 of the Model	3.0	-1.5	-1.0	-0.7	-0.4	-0.1	0.2	0.6	0.9	1.5
5% Payment Adjustment For Performance Year 2 of the Model	5.0	-2.5	-1.6	-1.1	-0.7	-0.1	0.4	0.9	1.5	2.6
6% Payment Adjustment For Performance Year 3 of the Model	6.0	-2.9	-2.0	-1.3	-0.8	-0.2	0.4	1.1	1.8	3.1
7% Payment Adjustment For Performance Year 4 of the Model	7.0	-3.4	-2.3	-1.5	-0.9	-0.2	0.5	1.3	2.1	3.6
8% Payment Adjustment For Performance Year 5 of the Model	8.0	-3.9	-2.6	-1.8	-1.1	-0.2	0.6	1.5	2.4	4.1

TABLE 58—HHA COHORT PAYMENT ADJUSTMENT DISTRIBUTIONS BY STATE/COHORT
[Based on a 3-percent payment adjustment]

Cohort	# of HHAs	Average payment adj. %	10%	20%	30%	40%	50%	60%	70%	80%	90%
HHA Cohort in States with no small cohorts (percent)											
MD	51	0.0	-1.0	-0.8	-0.6	-0.4	0.1	0.3	0.5	0.6	1.1
NC	167	-0.1	-1.3	-0.9	-0.6	-0.3	-0.1	0.1	0.4	0.7	0.9
TN	124	-0.2	-1.4	-0.9	-0.7	-0.5	-0.1	0.1	0.5	0.7	1.0
WA	57	-0.2	-1.1	-0.9	-0.6	-0.3	0.0	0.2	0.3	0.4	0.7
Smaller-volume HHA Cohort in states with small cohort (percent)											
AZ	8	-0.4	-2.4	-1.7	-1.3	-1.1	-1.0	-0.9	0.4	1.4	2.1
FL	103	0.2	-1.7	-1.3	-0.8	-0.5	-0.2	0.6	1.1	1.6	2.9
IA	32	0.0	-1.4	-1.0	-0.7	-0.5	-0.2	0.2	0.6	1.1	1.3
MA	23	-0.7	-2.6	-2.0	-1.7	-1.5	-1.3	-0.9	0.1	1.2	1.2
NE	16	0.4	-1.8	-1.3	-1.2	-0.7	0.5	1.0	1.8	2.4	3.1
Large-volume HHA Cohort in states with small cohorts (percent)											
AZ	105	-0.1	-1.5	-1.0	-0.7	-0.5	-0.3	0.2	0.6	0.7	1.2
FL	723	0.1	-1.4	-0.9	-0.6	-0.3	0.0	0.3	0.7	1.1	1.8
IA	94	-0.1	-1.5	-1.1	-0.7	-0.4	-0.2	0.1	0.5	0.9	1.4
MA	111	-0.2	-1.6	-1.2	-0.8	-0.5	-0.3	0.1	0.3	0.7	1.1
NE	44	0.1	-1.3	-0.9	-0.5	-0.1	0.2	0.3	0.7	0.9	1.1

TABLE 59—PAYMENT ADJUSTMENT DISTRIBUTIONS BY CHARACTERISTICS
[Based on a 3-percent payment adjustment] ^{230 231}

Cohort	# of HHAs	Average payment adj. %	10%	20%	30%	40%	50%	60%	70%	80%	90%
Small HHA (<60 patients in CY 2015)	189	0.1	-1.8	-1.4	-1.0	-0.6	-0.2	0.5	1.1	1.3	2.6
Large HHA (≥60 patients in CY 2015)	1,469	0.0	-1.4	-1.0	-0.6	-0.4	-0.1	0.2	0.5	0.8	1.5
Low % Dually—Eligible	414	0.1	-1.1	-0.8	-0.5	-0.2	0.1	0.4	0.6	0.9	1.4
Medium % Dually—Eligible	830	-0.1	-1.4	-1.0	-0.7	-0.4	-0.2	0.1	0.4	0.7	1.2
High % Dually—Eligible	414	0.1	-1.7	-1.3	-0.8	-0.5	0.0	0.4	0.9	1.5	2.3
Low Acuity	415	-0.3	-1.8	-1.4	-1.0	-0.7	-0.5	-0.1	0.2	0.6	1.2
Mid Acuity	828	0.0	-1.3	-0.9	-0.6	-0.4	-0.1	0.2	0.5	0.8	1.4
High Acuity	414	0.4	-1.1	-0.6	-0.3	0.0	0.3	0.6	0.9	1.3	2.2
All non-rural beneficiaries	989	0.1	-1.5	-1.0	-0.7	-0.4	0.0	0.3	0.7	1.1	1.9
Up to 35% rural beneficiaries	389	-0.1	-1.5	-1.0	-0.6	-0.4	-0.1	0.1	0.4	0.7	1.1
Over 35% rural beneficiaries	280	-0.1	-1.4	-1.0	-0.7	-0.5	-0.2	0.0	0.4	0.8	1.3
Non-Profit HHAs	304	0.1	-1.2	-0.8	-0.6	-0.3	0.0	0.3	0.6	0.9	1.4
For-Profit HHAs	1,238	0.0	-1.5	-1.0	-0.7	-0.4	-0.1	0.2	0.6	0.9	1.6
Government HHAs	116	-0.1	-1.3	-1.0	-0.7	-0.5	-0.3	0.0	0.3	0.6	1.2
Freestanding	1,494	0.0	-1.5	-1.0	-0.7	-0.4	-0.1	0.2	0.6	0.9	1.6
Facility-based	164	0.0	-1.2	-0.9	-0.5	-0.3	0.0	0.3	0.5	0.8	1.2

TABLE 60—IMPACT OF CHANGING MINIMUM REQUIRED SAMPLE SIZE FOR HHCAHPS PERFORMANCE MEASURES ON AVERAGE TPS AND PAYMENT ADJUSTMENT RANGE ²³²

State	HHA count	Average TPS				Minimum payment adjustment		Maximum payment adjustment	
		20 Minimum	40 Minimum	Difference	% Dif- ference	20 Minimum (%)	40 Minimum (%)	20 Minimum (%)	40 Minimum (%)
Larger-Volume HHAS									
AZ	105	38.393	39.254	0.86	2.2	−2.6	−2.6	3.0	3.0
FL	723	36.794	37.451	0.657	1.8	−2.6	−2.6	3.0	3.0
IA	94	41.079	41.049	−0.03	−0.1	−2.4	−2.4	2.0	3.0
MA	111	40.074	39.927	−0.147	−0.4	−2.8	−2.8	2.6	2.6
MD	50	47.287	47.517	0.23	0.5	−1.2	−1.2	2.0	2.4
NC	164	43.738	44.175	0.437	1.0	−2.0	−2.0	2.2	2.2
NE	44	39.714	40.581	0.867	2.1	−1.8	−1.8	2.9	2.7
TN	121	45.699	45.749	0.05	0.1	−2.8	−2.6	1.8	1.8
WA	57	49.888	49.685	−0.203	−0.4	−1.4	−1.8	1.2	1.2
Total	1,469								
Smaller-Volume HHAS									
AZ	8	31.474	31.474	0	0.0	−2.4	−2.4	2.1	2.1
FL	103	37.349	37.349	0	0.0	−2.6	−2.6	3.0	3.0
IA	32	37.741	37.741	0	0.0	−1.9	−1.9	2.0	2.0
MA	23	26.904	26.904	0	0.0	−2.7	−2.7	3.0	3.0
MD	1	55.841	55.841	0	0.0	0.6	0.6	0.6	0.6
NC	3	67.1	67.1	0	0.0	−0.2	−0.2	3.0	3.0
NE	16	37.076	37.076	0	0.0	−2.8	−2.8	3.0	3.0
TN	3	48.549	48.549	0	0.0	−1.4	−1.4	2.3	2.3
Total	189								
Total	1,658								

4. HH QRP

Failure to submit data required under section 1895(b)(3)(B)(v) of the Act will result in the reduction of the annual update to the standard federal rate for discharges occurring during such fiscal year by 2 percentage points for any HHA that does not comply with the requirements established by the Secretary. At the time that this analysis was prepared, 513, or approximately 4.3 percent, of the 12,149 active Medicare-certified HHAs, did not receive the full annual percentage increase for the CY 2017 annual payment update determination. Information is not available to determine the precise number of HHAs that will not meet the

requirements to receive the full annual percentage increase for the CY 2018 payment determination.

As noted in section VII.B. of this proposed rule, the net effect of our proposals is an estimated decrease in cost associated with proposed changes to the HH QRP on average of \$3,700.74 per HHA annually, or \$44,952,846.87 for all HHAs annually.

D. Alternatives Considered

1. HH PPS for CY 2018

We did not consider extending the rural add-on payment as this provision was statutory. Section 421(a) of the MMA extended the rural add-on by providing an increase of 3 percent of the payment amount otherwise made under section 1895 of the Act for HH services provided in a rural area, for episodes and visits ending before January 1, 2018. Therefore, for episodes and visits that end on or after January 1, 2018, a rural add-on payment will not apply.

In the alternatives considered section for the CY 2016 HH PPS proposed rule (80 FR 39839), we considered reducing the 60-day episode rate in CY 2016 only to account for nominal case-mix growth between CY 2012 and CY 2014. However, we instead proposed to

reduce the 60-day episode rate over a 2-year period (CY 2016 and CY 2017) to lessen the impact on HHAs in a given year. In the CY 2016 HH PPS final rule (80 FR 68624), we finalized a reduction of 0.97 percent to the 60-day episode rate in each of the next 3 calendar years (CY 2016 through CY 2018). Therefore, the alternatives with regards to the 0.97 percent reduction in the national, standardized 60-day episode payment amount for CY 2018 were already considered in the CY 2016 HH PPS proposed and final rules and we did not consider alternatives for implementing this reduction for CY 2018.

We are not able to consider alternative values for the home health payment update percentage. The home health payment update percentage is based on the home health market basket update and section 1895(b)(3)(B) of the Act, as amended by section 411(d) of the MACRA, mandates that for home health payments for CY 2018, the market basket percentage increase shall be 1 percent.

2. HH PPS for CY 2019 (Proposed HHGM)

We considered proposing to implement the HHGM for CY 2018.

²³⁰ Rural beneficiaries identified based on the CBSA code reported on the claim.

²³¹ Acuity is based on the average case-mix weight for non-LUPA episodes. Low acuity is defined as the bottom 25% (among HHVBP model participants); mid-acuity is the middle 50% and high acuity is the highest 25%. Note that one HHA was missing acuity information.

²³² OASIS measures run from January 1, 2015 to December 31, 2016; Claims from September 1, 2015 to September 30, 2016. Payment based on 2015 and 2016 Medicare claims data (2016 is used as the payment year—in actuality CY 2018 claims payments would determine actual payment adjustment amounts).

However, implementation of the HHGM will require provider education and training, updating and revising relevant manuals, and changing assessment and claims processing systems. Implementation starting in 2019 would provide an opportunity for CMS and providers to prepare.

For CY 2019, in addition to considering whether to implement the HHGM in a fully non-budget neutral manner for CY 2019 or implementing the HHGM with a HHGM partial budget neutrality adjustment factor that would have reduced the estimated impact of the HHGM by 50 percent in CY 2019 and the elimination of such factor in CY 2020, we also considered implementing the HHGM as fully budget neutral in CY 2019 or as partially budget-neutral with longer phase-out period (for example starting with a HHGM partial budget neutrality adjustment factor that would have reduced the estimated impact of the HHGM by 75 percent in CY 2019, a HHGM partial budget neutrality adjustment factor that would have reduced the estimated impact of the HHGM by 50 percent in CY 2020, a HHGM partial budget neutrality adjustment factor that would have reduced the estimated impact of the HHGM by 25 percent in CY 2021, and the elimination of such factor in CY 2022). However, we propose to implement the change in the unit of payment under the HHGM in a non-budget neutral manner as doing so better aligns home health payments with the costs of providing care. In addition, we do not believe a longer phase-out period is necessary if we were to implement the HHGM in a non-budget neutral manner with a HHGM partial budget neutrality adjustment factor applied in CY 2019 to be removed in CY 2020, as this 2-year timeframe would be sufficient to lessen the economic impact in the first year of implementation.

We also considered maintaining 60-day episodes of care as the unit of payment. As stated in the FY 2001 HH PPS final rule, “We believe the 60-day episode definition is the most appropriate approach to define the unit of payment under HHA PPS. Public support for the 60-day episode as the unit of payment under PPS centered on the general consensus that HHAs and physicians predict home care needs over a 60-day timeframe due to current plan of care requirements and required updates to the comprehensive assessments that basically follow a 60-day timeframe. As discussed in detail in the proposed rule, research indicated that the 60-day episode captures the majority of stays experienced in the

Phase II per-episode HHA PPS demonstration (65 FR 41136).” However, we further noted that we “will continue to monitor the appropriateness of the 60-day unit of payment and may consider modifying our approach to the episode definition in subsequent years of PPS, if warranted.” During subsequent years, we have identified variation in average resource use between the first 30-day period within a 60-day episode and the second 30-day period within a 60-day episode. This difference in resources between the first and second 30-day periods within a 60-day episode led to the development of 30-day periods for the HHGM. In addition, the accuracy of the HHGM improves when a shorter, more constrained time period is examined. This in turn would improve the accuracy of the case-mix weights that are generated using 30-day periods instead of 60-day episodes. We note that the frequency of the required updates to the plan of care and the comprehensive assessment would remain unchanged under the proposed HHGM.

We considered whether to continue using the wage-weighted minutes of care (WWMC) approach to estimate resource use under the HHGM, as described in section III.E.2 of this proposed rule. Although the relationship in relative costs between the WWMC approach and the proposed cost-per-minute plus non-routine supplies (CPM+NRS) approach is very similar (correlation coefficient equal to 0.8016), the WWMC approach does not as evenly weight skilled nursing costs relative to therapy costs as evidenced in the cost report data and would require us to maintain a separate case-mix adjustment mechanism for NRS. If we were to maintain the current WWMC approach, skilled nursing and therapy costs would not be as evenly weighted and a certain level of complexity in calculating payments under the HH PPS would persist as we would need to continue with the current method of case-mix adjusting NRS payments separate from service costs (*i.e.*, skilled nursing, physical therapy, occupational therapy, speech-language pathology, home health aide, and medical social services) under the HH PPS.

Finally, we considered not proposing the HH PPS case-mix methodology refinements for CY 2019. However, in maintaining the current case-mix methodology, the current payment system, with its various therapy thresholds, would continue to provide financial incentives that detract from a focus on patient characteristics and care needs when agencies are setting plans of care for their patients, and would

continue to incentivize unnecessary therapy utilization. The proposed HHGM removes therapy thresholds from the case-mix adjustment methodology thereby eliminating the financial incentive to provide unnecessary therapy visits in order to maximize payment. In addition, we believe the proposed HHGM is a more simplified, clinically intuitive, and patient-centered approach to payment compared to the existing case-mix adjustment methodology. We invite comments on the alternatives discussed in this analysis.

3. HHVBP Model Proposals

An alternative to our proposal to use 40 completed HHCAHPS surveys beginning with PY 1 would be to continue calculating quality scores at 20 completed HHCAHPS surveys as finalized in the CY 2016 HH PPS final rule.

Another alternative would be to use 40 completed HHCAHPS surveys beginning with PY 2 and subsequent years, but keep the 20 completed HHCAHPS surveys calculation for PY 1; however, this would give HHAs a short amount of time to analyze from year to year a change in threshold from 20 to 40 completed HHCAHPS surveys.

Rather than removing the Drug Education on All Medications Provided to Patient/Caregiver during all Episodes of Care measure from the set of applicable measures, an alternative would be to keep the measure in the set of applicable measures for the HHVBP Model. Doing so would continue HHAs' awareness of the importance of drug education for patient and caregivers during all episodes of care. Nevertheless, there would be a lack of variability in the measure across the participating HHAs and the measure does not address the quality or intensity of the education provided.

E. Accounting Statement and Table

As required by OMB Circular A-4 (available at http://www.whitehouse.gov/omb/circulars/a004_a-4), in Tables 61 and 62, we have prepared an accounting statement showing the classification of the transfers and costs associated with the HH PPS provisions of this proposed rule. Table 61 provides our best estimate of the decrease in Medicare payments under the HH PPS as a result of the changes presented in this proposed rule for the HH PPS provisions in CY 2018. Table 62 provides our estimate as a result of the changes associated with the HHGM proposed for CY 2019. Table 63 provides our best estimates of the

changes associated with the HH QRP proposals.

TABLE 61—ACCOUNTING STATEMENT: HH PPS CLASSIFICATION OF ESTIMATED TRANSFERS, FROM CYs 2017 TO 2018

Category	Transfers
Annualized Monetized Transfers.	—\$80 million.

TABLE 61—ACCOUNTING STATEMENT: HH PPS CLASSIFICATION OF ESTIMATED TRANSFERS, FROM CYs 2017 TO 2018—Continued

Category	Transfers
From Whom to Whom?	Federal Government to HHAs.

TABLE 62—ACCOUNTING STATEMENT: HH PPS CLASSIFICATION OF ESTIMATED TRANSFERS DUE TO IMPLEMENTATION OF PROPOSED HHGM, FROM CYs 2018 TO 2019

Category	Transfers
Annualized Monetized Transfers (Not Budget Neutral)	—\$950 million.
Annualized Monetized Transfers (Partially Budget Neutral)	—\$480 million.
From Whom to Whom?	Federal Government to HHAs.

TABLE 63—ACCOUNTING STATEMENT: HH QRP CLASSIFICATION OF ESTIMATED COSTS, FROM CYs 2018 TO 2019

Category	Costs
Annualized Monetized Net Burden for HHAs Submission of the OASIS	—\$44.9 million.

F. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, entitled Reducing Regulation and Controlling Regulatory Costs (82 FR 9339), was issued on January 30, 2017. Under E.O. 13771, this rule would be considered deregulatory if finalized as proposed.

G. Conclusion

1. HH PPS

In conclusion, we estimate that the net impact of the HH PPS policies in this rule is a decrease of 0.4 percent, or \$80 million, in Medicare payments to HHAs for CY 2018. The —\$80 million impact reflects the effects of a 0.5 percent reduction in payments due to the sunset of the rural add-on provision (\$100 million decrease), a 1 percent CY 2018 HH payment update percentage (\$190 million increase), and a 0.9 percent decrease in payments due to the 0.97 percent reduction to the national, standardized 60-day episode payment rate in CY 2017 to account for nominal case-mix growth (\$170 million decrease). We estimate that the net impact of the proposed HHGM is a decrease of 4.3 percent (\$950 million decrease) in Medicare payments to HHAs in CY 2019 if the proposed HHGM is implemented in a fully non-budget neutral manner. We estimate that the net impact of the proposed HHGM is a decrease of 2.2 percent (\$480 million decrease) in Medicare payments to HHAs in CY 2019 if the proposed HHGM is implemented in a partially budget-neutral manner in CY 2019 with

the removal of the HHGM partial budget neutrality adjustment factor in CY 2020.

This analysis, together with the remainder of this preamble, provides an initial Regulatory Flexibility Analysis.

2. HHVBP Model

In conclusion, we estimate there would be no net impact (to include either a net increase or reduction in payments) in this proposed rule in Medicare payments to HHAs competing in the HHVBP Model for CY 2018. However, the overall economic impact of the HHVBP Model provision is an estimated \$378 million in total savings from a reduction in unnecessary hospitalizations and SNF usage as a result of greater quality improvements in the home health industry over the life of the HHVBP Model.

3. HH QRP

In conclusion, for CY 2019 we estimate that there will be a total decrease in costs of \$44,952,846.87 associated with the proposed changes to the HH QRP.

X. Federalism Analysis

Executive Order 13132 on Federalism (August 4, 1999) establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. We have reviewed this proposed rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it will not have

substantial direct effects on the rights, roles, and responsibilities of states, local or tribal governments.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 484

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 409—HOSPITAL INSURANCE BENEFITS

- 1. The authority citation for part 409 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Act (42 U.S.C. 1302 and 1395hh).

- 2. Section § 409.43 is amended by—

- a. Revising paragraphs (c)(2) and (c)(3)(ii);
- b. In paragraph (e)(1)(iii), removing the phrase “during the 60-day episode” and adding in its place the phrase “within 60 days after discharge”.

The revisions read as follows:

§ 409.43 Plan of care requirements.

* * * * *

(c) * * *

(2) *Reduction or disapproval of anticipated payment requests.* CMS has

the authority to reduce or disapprove requests for anticipated payments in situations when protecting Medicare program integrity warrants this action. Since the request for anticipated payment is based on verbal orders as specified in paragraph (c)(1)(i) of this section and/or a prescribing referral as specified in paragraph (c)(1)(ii) of this section and is not a Medicare claim for purposes of the Act (although it is a “claim” for purposes of Federal, civil, criminal, and administrative law enforcement authorities, including but not limited to the Civil Monetary Penalties Law (as defined in 42 U.S.C. 1320a–7a(i)(2)), the Civil False Claims Act (as defined in 31 U.S.C. 3729(c)), and the Criminal False Claims Act (18 U.S.C. 287)), the request for anticipated payment will be canceled and recovered unless the claim is submitted within the greater of one of the following:

(i) 60 days from the end of the episode (for claims beginning on or before December 31, 2018);

(ii) 60 days from the end of the 30-day period of care (for claims beginning on or after January 1, 2019); or

(iii) 60 days from the issuance of the request for anticipated payment.

(3) * * *

(ii) Before the claims for each episode (for a 60-day episode of care beginning on or before December 31, 2018) or period (for a 30-day period of care beginning on or after January 1, 2019) for services is submitted for the final percentage prospective payment.

* * * * *

PART 484—HOME HEALTH SERVICES

■ 3. The authority citation for part 484 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Act (42 U.S.C. 1302 and 1395(hh)) unless otherwise indicated.

■ 4. Section 484.202 is amended by revising the definitions of “Rural area” and “Urban area” to read as follows:

§ 484.202 Definitions.

* * * * *

Rural area means an area defined in § 412.64(b)(1)(ii)(C) of this chapter.

Urban area means an area defined in § 412.64(b)(1)(ii)(A) and (B) of this chapter.

■ 5. Section 484.205 is revised to read as follows:

§ 484.205 Basis of payment.

(a) *Method of payment.* An HHA receives a national, standardized prospective payment amount for home health services previously paid on a reasonable cost basis (except the osteoporosis drug defined in section

1861(kk) of the Act) as of August 5, 1997. The national, standardized prospective payment is determined in accordance with § 484.215.

(b) *Unit of payment.* For episodes beginning on or before December 31, 2018, an HHA receives a national, standardized prospective 60-day episode payment amount. For periods beginning on or after January 1, 2019, a HHA receives a national, standardized prospective 30-day payment amount.

(c) *OASIS data.* A HHA must submit to CMS the OASIS data described at § 484.55(b) and (d) in order for CMS to administer the payment rate methodologies described in §§ 484.215, 484.220, 484.230, 484.235, and 484.240.

(d) *Payment adjustments.* The national, standardized prospective payment amount is subject to the following adjustments and additional payments:

(1) A low-utilization payment adjustment (LUPA) of a predetermined per-visit rate as specified in § 484.230.

(2) A partial payment adjustment as specified in § 484.235.

(3) An outlier payment as specified in § 484.240.

(e) *Medical review.* All payments under this system may be subject to medical review with respect to beneficiary eligibility, medical necessity, and case-mix group assignment.

(f) *Durable medical equipment (DME) and disposable devices.* DME provided as a home health service as defined in section 1861(m) of the Act is paid the fee schedule amount. Separate payment is made for “furnishing NPWT using a disposable device,” as that term is defined in § 484.202, and is not included in the national, standardized prospective payment amount.

(g) *Split percentage payments.* Split percentage payments are made in accordance with requirements at § 409.43(c) of this chapter.

(1) Split percentage payments for episodes beginning on or before December 31, 2018:

(i) The initial payment for initial episodes is paid to an HHA at 60 percent of the case-mix and wage-adjusted 60-day episode rate. The residual final payment for initial episodes is paid at 40 percent of the case-mix and wage-adjusted 60-day episode rate.

(ii) The initial payment for subsequent episodes is paid to an HHA at 50 percent of the case-mix and wage-adjusted 60-day episode rate. The residual final payment for subsequent episodes is paid at 50 percent of the case-mix and wage-adjusted 60-day episode rate.

(2) Split percentage payments for periods beginning on or after January 1, 2019:

(i) The initial payment for initial 30-day periods is paid to an HHA at 60 percent of the case-mix and wage-adjusted 30-day payment rate. The residual final payment for initial 30-day periods is paid at 40 percent of the case-mix and wage-adjusted 30-day payment rate.

(ii) The initial payment for subsequent 30-day periods is paid to an HHA at 50 percent of the case-mix and wage-adjusted 30-day payment rate. The residual final payment for subsequent 30-day periods is paid at 50 percent of the case-mix and wage-adjusted 30-day payment rate.

§ 484.210 [Removed and Reserved]

■ 6. Section 484.210 is removed and reserved.

■ 7. Section 484.215 is amended by—

■ a. Revising the section heading;

■ b. Revising paragraph (d) introductory text; and

■ c. Adding paragraph (f).

The revisions and addition read as follows:

§ 484.215 Initial establishment of the calculation of the national, standardized prospective 60-day episode payment and 30-day payment rates.

* * * * *

(d) *Calculation of the unadjusted national average prospective payment amount for the 60-day episode.* For episodes beginning on or before December 31, 2018, CMS calculates the unadjusted national 60-day episode payment in the following manner:

* * * * *

(f) *For periods beginning on or after January 1, 2019, a national, standardized prospective 30-day payment rate applies.* The national, standardized prospective 30-day payment rate is an amount determined by the Secretary, as subsequently updated pursuant to § 484.225.

■ 8. Section 484.220 is amended by—

■ a. Revising the section heading;

■ b. Revising the introductory text; and

■ c. In paragraph (a) introductory text, removing the phrase “national prospective 60-day episode” and adding in its place the phrase “national, standardized prospective”.

The revisions read as follows:

§ 484.220 Calculation of the case-mix and wage area adjusted prospective payment rates.

CMS adjusts the national, standardized prospective payment rates as referenced in § 484.215 to account for the following:

* * * * *

- 9. Section 484.225 is amended by—
- a. Revising the section heading;
- b. Revising paragraph (a);
- c. In paragraphs (b) and (c), removing the phrase “national prospective 60-day episode” and adding the phrase “national standardized prospective”; and
- d. Adding paragraph (d).

The revisions and addition read as follows:

§ 484.225 Annual update of the unadjusted national, standardized prospective payment rates.

(a) CMS annually updates the unadjusted national, standardized prospective payment rate on a calendar year basis in accordance with section 1895(b)(3)(B) of the Act.

* * * * *

(d) For CY 2019, the national, standardized prospective 30-day payment amount is an amount determined by the Secretary. CMS annually updates this amount on a calendar year basis in accordance with paragraphs (a) through (c) of this section.

■ 10. Section 484.230 is revised to read as follows:

§ 484.230 Low-utilization payment adjustments.

(a) For episodes beginning on or before December 31, 2018, an episode with four or fewer visits is paid the national per-visit amount by discipline updated annually by the applicable market basket for each visit type, in accordance with § 484.225. The national per-visit amount is adjusted by the appropriate wage index based on the site of service of the beneficiary. An amount will be added to the low-utilization payment adjustments for low-utilization episodes that occur as the beneficiary's only episode or initial episode in a sequence of adjacent episodes. For purposes of the home health PPS, a sequence of adjacent episodes for a beneficiary is a series of claims with no more than 60 days without home care between the end of one episode, which is the 60th day (except for episodes that have been PEP-adjusted), and the beginning of the next episode.

(b) For periods beginning on or after January 1, 2019, an HHA receives a national 30-day payment of a predetermined rate for home health services, unless CMS determines at the end of the 30-day period that the HHA furnished minimal services to a patient during the 30-day period. For each payment group used to case-mix adjust the 30-day payment rate, the 10th percentile value of total visits during a

30-day period of care will be used to create payment group specific thresholds with a minimum threshold of at least 2 visits for each case-mix group. A 30-day period with a total number of visits less than the threshold is paid the national per-visit amount by discipline updated annually by the applicable market basket for each visit type. The national per-visit amount is adjusted by the appropriate wage index based on the site of service for the beneficiary.

(c) An amount will be added to low-utilization payment adjustments for low-utilization periods that occur as the beneficiary's only 30-day period or initial 30-day period in a sequence of adjacent periods of care. For purposes of the home health PPS, a sequence of adjacent periods of care for a beneficiary is a series of claims with no more than 60 days without home care between the end of one period, which is the 30th day (except for episodes that have been partial payment adjusted), and the beginning of the next episode.

■ 11. Section 484.235 is revised to read as follows:

§ 484.235 Partial payment adjustments.

(a) *Partial episode payments (PEPs) for episodes beginning on or before December 31, 2018.* (1) An HHA receives a national, standardized 60-day payment of a predetermined rate for home health services unless CMS determines that an intervening event has occurred, which warrants a new 60-day episode for purposes of payment. A start of care OASIS assessment and physician certification of the new plan of care are required. An intervening event is defined as either a beneficiary elected transfer or a discharge with goals met or no expectation of return to home health, but the beneficiary returned to home health during the 60-day episode.

(2) The PEP adjustment will not apply in situations of transfers among HHAs under common ownership. Those situations will be considered services provided under arrangement on behalf of the originating HHA by the receiving HHA with the common ownership interest for the balance of the 60-day episode. The common ownership exception to the transfer PEP adjustment does not apply if the beneficiary moves to a different MSA or Non-MSA during the 60-day episode before the transfer to the receiving HHA. The transferring HHA in situations of common ownership not only serves as a billing agent, but must also exercise professional responsibility over the arranged-for services in order for services provided under arrangements to be paid.

(3) If the intervening event warrants a new 60-day payment and a new physician certification and a new plan of care, the initial HHA receives a partial episode payment adjustment reflecting the length of time the patient remained under its care based on the first billable visit date through and including the last billable visit date. The PEP is calculated by determining the actual days served as a proportion of 60 multiplied by the initial 60-day payment amount.

(b) *Partial payment adjustments for periods beginning on or after January 1, 2019.* (1) An HHA receives a national, standardized 30-day payment of a predetermined rate for home health services unless CMS determines that an intervening event has occurred, which warrants a new 30-day period for purposes of payment. A start of care OASIS assessment and physician certification of the new plan of care are required. An intervening event is defined as either a beneficiary elected transfer or a discharge and return to home health during the 30-day period.

(2) The partial payment adjustment will not apply in situations of transfers among HHAs of common ownership. Those situations will be considered services provided under arrangement on behalf of the originating HHA by the receiving HHA with the common ownership interest for the balance of the 30-day period. The common ownership exception to the transfer partial payment adjustment does not apply if the beneficiary moves to a different MSA or Non-MSA during the 30-day period before the transfer to the receiving HHA. The transferring HHA in situations of common ownership not only serves as a billing agent, but must also exercise professional responsibility over the arranged-for services in order for services provided under arrangements to be paid.

(3) If the intervening event warrants a new 30-day payment and thus a new physician certification and a new plan of care, the initial HHA receives a partial payment adjustment reflecting the length of time the patient remained under its care based on the first billable visit date through and including the last billable visit date. The partial payment is calculated by determining the actual days served as a proportion of 30 multiplied by the initial 30-day payment amount.

■ 12. Section 484.240 is revised to read as follows:

§ 484.240 Outlier payments.

(a) For episodes beginning on or before December 31, 2018, an HHA receives an outlier payment for an

episode whose estimated costs exceeds a threshold amount for each case-mix group. The outlier threshold for each case-mix group is the episode payment amount for that group, or the PEP adjustment amount for the episode, plus a fixed dollar loss amount that is the same for all case-mix groups.

(b) For periods beginning on or after January 1, 2019, an HHA receives an outlier payment for a 30-day period whose estimated cost exceeds a threshold amount for each case-mix group. The outlier threshold for each case-mix group is the 30-day payment amount for that group, or the partial payment adjustment amount for the 30-day period, plus a fixed dollar loss amount that is the same for all case-mix groups.

(c) The outlier payment is a proportion of the amount of estimated cost beyond the threshold.

(d) CMS estimates the cost for each episode by multiplying the national per-15 minute unit amount of each discipline by the number of 15 minute units in the discipline and computing the total estimated cost for all disciplines.

■ 13. Section 484.250 is amended by revising paragraph (a)(1) and adding paragraphs (d) through (f) to read as follows:

§ 484.250 Patient assessment data.

(a) * * *

(1) The OASIS data described at § 484.55(b) and (d) for CMS to administer the payment rate methodologies described in §§ 484.215, 484.220, 484.230, 484.235, and 484.240; and to meet the quality reporting requirements of section 1895(b)(3)(B)(v) of the Act.

* * * * *

(d) *Exceptions and extension requirements.* (1) A HHA may request and CMS may grant exceptions or extensions to the reporting requirements under section 1895(b)(3)(B)(v) of the Act for one or more quarters, when there are certain extraordinary circumstances beyond the control of the HHA.

(2) A HHA may request an exception or extension within 90 days of the date that the extraordinary circumstances occurred by sending an email to CMS HHAPU reconsiderations at

HHAPUReconsiderations@cms.hhs.gov that contains all of the following information:

(i) HHA CMS Certification Number (CCN).

(ii) HHA Business Name.

(iii) HHA Business Address.

(iv) CEO or CEO-designated personnel contact information including name, telephone number, title, email address, and mailing address (The address must be a physical address, not a post office box).

(v) HHA's reason for requesting the exception or extension.

(vi) Evidence of the impact of extraordinary circumstances, including, but not limited to, photographs, newspaper, and other media articles.

(vii) Date when the HHA believes it will be able to again submit data under section 1895(b)(3)(B)(v) of the Act and a justification for the proposed date.

(3) Except as provided in paragraph (d)(4) of this section, CMS will not consider an exception or extension request unless the HHA requesting such exception or extension has complied fully with the requirements in this paragraph (d).

(4) CMS may grant exceptions or extensions to HHAs without a request if it determines that one or more of the following has occurred:

(i) An extraordinary circumstance affects an entire region or locale.

(ii) A systemic problem with one of CMS's data collection systems directly affected the ability of a HHA to submit data under section 1895(b)(3)(B)(v) of the Act.

(e) *Reconsideration.* (1) HHAs that do not meet the quality reporting requirements under section 1895(b)(3)(B)(v) of the Act for a program year will receive a letter of non-compliance through the USPS and via notification in CASPER. An HHA may request reconsideration no later than 30 calendar days after the date identified on the letter of non-compliance.

(2) Reconsideration requests may be submitted to CMS by sending an email to CMS HHAPU reconsiderations at HHAPureConsiderations@cms.hhs.gov containing all of the following information:

(i) HHA CCN.

(ii) HHA Business Name.

(iii) HHA Business Address.

(iv) CEO or CEO-designated personnel contact information including name, telephone number, title, email address, and mailing address (The address must be a physical address, not a post office box).

(v) CMS identified reason(s) for non-compliance from the non-compliance letter.

(vi) Reason(s) for requesting reconsideration, including all supporting documentation. CMS will not consider an exception or extension request unless the HHA has complied fully with the requirements in paragraph (e)(2) of this section.

(3) CMS will make a decision on the request for reconsideration and provide notice of the decision to the HHA through CASPER and via letter sent through the United States Postal Service.

(f) *Appeals.* (1) A HHA that is dissatisfied with CMS' decision on a reconsideration request submitted under paragraph (e) of this section may file an appeal with the Provider Reimbursement Review Board (PRRB) under 42 CFR part 405, subpart R.

(2) [Reserved]

■ 14. Section 484.305 is amended by revising the definition of "Applicable measure" to read as follows:

§ 484.305 Definitions.

* * * * *

Applicable measure means a measure for which a competing HHA has provided a minimum of:

(1) 20 home health episodes of care per year for the OASIS-based measures;

(2) 20 home health episodes of care per year for the claims-based measures; or

(3) 40 completed surveys for the HHCAHPS measures.

* * * * *

Dated: June 29, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: June 30, 2017.

Thomas E. Price,

Secretary, Department of Health and Human Services.

[FR Doc. 2017-15825 Filed 7-25-17; 4:15 pm]

BILLING CODE 4120-01-P



FEDERAL REGISTER

Vol. 82

Friday,

No. 144

July 28, 2017

Part III

Securities and Exchange Commission

Public Company Accounting Oversight Board; Notice of Filing of Proposed Rules on the Auditor's Report on an Audit of Financial Statements When the Auditor Expresses an Unqualified Opinion, and Departures From Unqualified Opinions and Other Reporting Circumstances, and Related Amendments to Auditing Standards; Notice

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81187; File No. PCAOB–2017–01]

Public Company Accounting Oversight Board; Notice of Filing of Proposed Rules on the Auditor's Report on an Audit of Financial Statements When the Auditor Expresses an Unqualified Opinion, and Departures From Unqualified Opinions and Other Reporting Circumstances, and Related Amendments to Auditing Standards

July 21, 2017.

Pursuant to Section 107(b) of the Sarbanes-Oxley Act of 2002 (the “Act” or “Sarbanes-Oxley Act”), notice is hereby given that on July 19, 2017, the Public Company Accounting Oversight Board (the “Board” or “PCAOB”) filed with the Securities and Exchange Commission (the “Commission” or “SEC”) the proposed rules described in Items I and II below, which items have been prepared by the Board. The Commission is publishing this notice to solicit comments on the proposed rules from interested persons.

I. Board's Statement of the Terms of Substance of the Proposed Rules

On June 1, 2017, the Board adopted new rules and amendments to auditing standards (collectively, the “proposed rules”) to make the auditor's report more informative and relevant to investors and other financial statement users. The text of the proposed rules appears in Exhibit A to the SEC Filing Form 19b–4 and is available on the Board's Web site at <https://pcaobus.org/Rulemaking/Pages/Docket034.aspx> and at the Commission's Public Reference Room.

II. Board's Statement of the Purpose of, and Statutory Basis for, the Proposed Rules

In its filing with the Commission, the Board included statements concerning the purpose of, and basis for, the proposed rules and discussed any comments it received on the proposed rules. The text of these statements may be examined at the places specified in Item IV below. The Board has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements. In addition, the Board is requesting that the Commission approve the proposed rules and related amendments, with the exception of the requirements related to critical audit matters, pursuant to Section 103(a)(3)(C) of the Sarbanes-Oxley Act, for application to audits of emerging growth companies (“EGCs”),

as that term is defined in Section 3(a)(80) of the Securities Exchange Act of 1934 (“Exchange Act”). The Board's request is set forth in section D.

A. Board's Statement of the Purpose of, and Statutory Basis for, the Proposed Rules

(a) Purpose Summary

The Board has adopted a new auditor reporting standard, AS 3101, The Auditor's Report on an Audit of Financial Statements When the Auditor Expresses an Unqualified Opinion (the “final standard” or “AS 3101”) and related amendments to its auditing standards that will require the auditor to provide new information about the audit and make the auditor's report more informative and relevant to investors and other financial statement users. The final standard retains the pass/fail opinion of the existing auditor's report but makes significant changes to the existing auditor's report, including the following:

- Communication of critical audit matters—matters communicated or required to be communicated to the audit committee and that: (1) Relate to accounts or disclosures that are material to the financial statements; and (2) involved especially challenging, subjective, or complex auditor judgment;
- Disclosure of auditor tenure—the year in which the auditor began serving consecutively as the company's auditor; and
- Other improvements to the auditor's report—a number of other improvements to the auditor's report to clarify the auditor's role and responsibilities, and make the auditor's report easier to read.

The Board believes that adopting these requirements responds to the strong interest of investors for enhanced communication about the audit and is consistent with its mandate to “protect the interests of investors and further the public interest in the preparation of informative, accurate and independent audit reports.”¹

The Board has adopted the final standard after more than six years of outreach and public comment, including comments from members of the Board's Standing Advisory Group (“SAG”) and Investor Advisory Group (“IAG”). The Board has taken into consideration all comments and believes its approach responds to investor requests for additional

information about the financial statement audit without imposing requirements beyond the auditor's expertise or mandate.

Investors are the beneficiaries of the audit and the auditor's report is the primary means by which the auditor communicates with them. Currently, however, the auditor's report conveys little of the information obtained and evaluated by the auditor as part of the audit. And while the auditor's report has generally remained unchanged since the 1940s, companies' operations have become more complex and global, and the financial reporting frameworks have evolved toward an increasing use of estimates, including fair value measurements. As part of the audit, auditors often perform procedures involving challenging, subjective, or complex judgments, but the auditor's report does not communicate this information to investors. Stated differently, the auditor's report does little to address the information asymmetry between investors and auditors,² even though investors have consistently asked to hear more from the auditor, an independent third-party expert whose work is undertaken for their benefit.³ The Board believes that reducing the information asymmetry between investors and auditors should, in turn, reduce the information asymmetry between investors and management. Outside the United States, other regulators and standard setters have already adopted expanded auditor reporting.

The communication of critical audit matters will inform investors and other financial statement users of matters arising from the audit that involved especially challenging, subjective, or complex auditor judgment, and how the auditor addressed these matters. The Board believes that these matters will

² Economists often describe this imbalance, where one party has more or better information than another party, as “information asymmetry.” As part of the system of financial reporting, the audit of the financial statements helps reduce the information asymmetry investors face by providing an independent opinion about whether the financial statements are presented fairly in all material respects.

³ See PCAOB IAG survey, Improving the Auditor's Report (Mar. 16, 2011) (“IAG 2011 survey”). See also CFA Institute's Usefulness of the Independent Auditor's Report Survey Results (May 4, 2011), Independent Auditor's Report Survey Results (Mar. 31, 2010), and Independent Auditor's Report Monthly Poll Results (Mar. 12, 2008) (“CFA survey and poll results”). See also Board public meeting transcripts and participant statements (Apr. 2–3, 2014), available on the Board's Web site in Rulemaking Docket Matter No. 034, Proposed Auditing Standards on the Auditor's Report and the Auditor's Responsibilities Regarding Other Information and Related Amendments (“Docket 034”).

¹ Section 101(a) of the Sarbanes-Oxley Act of 2002 (“Sarbanes-Oxley”), 15 U.S.C. 7211(a).

likely be identified in areas that investors have indicated would be of particular interest to them, such as significant management estimates and judgments made in preparing the financial statements; areas of high financial statement and audit risk; significant unusual transactions; and other significant changes in the financial statements. The final standard is designed to elicit more information about the audit directly from the auditor. The Board believes that the critical audit matter requirements will respond to requests from investors for more information from the auditor while appropriately addressing concerns raised by other commenters.

Investors and investor advocates have suggested a variety of ways in which investors can use the information provided in critical audit matters. In the view of some investors, critical audit matters will add to the total mix of information, providing insights relevant in analyzing and pricing risks in capital valuation and allocation, and contributing to their ability to make investment decisions. Investors also stated that critical audit matters will focus their attention on key financial reporting areas and identify areas that deserve more attention, enhancing the efficiency of investors and others in the consumption of financial information. Some investors believe that critical audit matters will highlight areas that they may wish to emphasize in their engagement with the company and provide important information that they can use in making proxy voting decisions, including ratification of the appointment of auditors.

The final standard also includes a new required statement in the auditor's report disclosing the year in which the auditor began serving consecutively as the company's auditor, as well as a number of other improvements to the auditor's report, such as a statement regarding the requirement for the auditor to be independent. Requiring disclosure of auditor tenure in the auditor's report will make this information readily accessible in a timely way for investors who find it useful. The other improvements to the auditor's report are intended to enhance the user's understanding of the auditor's role and responsibilities related to the audit of the financial statements, make the auditor's report easier to read, and provide a consistent format.

The final standard will generally apply to audits conducted under PCAOB standards. However, communication of critical audit matters is not required for audits of brokers and dealers reporting under the Securities

Exchange Act of 1934 (the "Exchange Act") Rule 17a-5; investment companies other than business development companies; employee stock purchase, savings, and similar plans ("benefit plans"); and emerging growth companies ("EGCs"), as defined in Section 3(a)(80) of the Exchange Act. Auditors of these entities may choose to include critical audit matters in the auditor's report voluntarily. The other requirements of the final standard will apply to these audits.

Critical audit matters are determined using a principles-based framework and the Board anticipates that the level of auditor effort will depend on the nature and complexity of the audit.

The Board has adopted a phased approach to the effective dates for the new requirements to provide accounting firms, companies, and audit committees more time to prepare for implementation of the critical audit matter requirements, which are expected to require more effort to implement than the additional improvements to the auditor's report. Subject to approval by the Securities and Exchange Commission ("SEC"), the final standard and amendments will take effect as follows:

- All provisions other than those related to critical audit matters will take effect for audits of fiscal years ending on or after December 15, 2017; and
- Provisions related to critical audit matters will take effect for audits of fiscal years ending on or after June 30, 2019, for large accelerated filers; and for fiscal years ending on or after December 15, 2020, for all other companies to which the requirements apply.

Auditors may elect to comply before the effective date, at any point after SEC approval of the final standard.

(b) Statutory Basis

The statutory basis for the proposed rules is Title I of the Act.

B. Board's Statement on Burden on Competition

Not applicable.

C. Board's Statement on Comments on the Proposed Rules Received From Members, Participants or Others

The Board released the proposed rule amendment for public comment in *Concept Release on Possible Revisions to PCAOB Standards Related to Reports on Audited Financial Statements; and Related Amendments to PCAOB Standards*, PCAOB Release No. 2011-003 (June 21, 2011) ("concept release"), *Proposed Auditing Standards—The Auditor's Report on an Audit of Financial Statements When the Auditor*

Expresses an Unqualified Opinion; The Auditor's Responsibilities Regarding Other Information in Certain Documents Containing Audited Financial Statements and the Related Auditor's Report; and Related Amendments to PCAOB Standards, PCAOB Release No. 2013-005 (Aug. 13, 2013) ("proposal"), *Proposed Auditing Standard—The Auditor's Report on an Audit of Financial Statements When the Auditor Expresses an Unqualified Opinion and Related Amendments to PCAOB Standards*, PCAOB Release No. 2016-003 (May 11, 2016) ("reproposal"). See Exhibit 2(a)(A). A copy of Release Nos. 2011-003, 2013-005, 2016-003 and the comment letters received in response to the PCAOB's requests for comment are available on the PCAOB's Web site at <https://pcaobus.org/Rulemaking/Pages/Docket034.aspx>. The Board received 491 written comment letters. The Board's response to the comments it received and the changes made to the rules in response to the comments received are discussed below.

Discussion of the Final Standard

Critical Audit Matters

Under the final standard, the auditor will be required to communicate critical audit matters in the auditor's report in order to provide more information about the audit and make the auditor's report more informative and relevant to investors and other financial statement users.

Investor, investor advocate, and analyst commenters generally supported the repromulgated requirement to communicate critical audit matters. Some of them stated that the communication of critical audit matters would be relevant to investors and other financial statement users by informing them of issues identified in the audit that were significant to the auditor, focusing attention on issues that would be pertinent to understanding the financial statements, and enhancing investor confidence in the financial statements.

The larger and some smaller accounting firms generally supported including critical audit matters in the auditor's report with some modification of the repromulgated requirements. Other commenters, including other smaller accounting firms, companies, and audit committee members, did not support the requirements. Some of these commenters asserted that critical audit matters would not provide relevant information to investors, may be duplicative of the company's disclosure, may result in disclosing information not otherwise required to be disclosed,

could increase cost, or could delay completion of the audit.

Other commenters suggested that the Board align the definition of critical audit matters with the International Auditing and Assurance Standards Board's ("IAASB") definition of key audit matters to enhance overall consistency.

Consistent with the Board's statutory mandate under Section 101(a) of Sarbanes-Oxley and in response to the 2008 U.S. Department of the Treasury Advisory Committee on the Auditing Profession ("ACAP") recommendation and continued investor support for expanded auditor reporting, the final standard includes the requirement to communicate critical audit matters substantially as repropoed. The Board has taken into consideration all comments, including concerns raised by some commenters, which are described in more detail below, and believes its approach responds to investor requests for additional information about the financial statement audit without imposing requirements beyond the auditor's expertise or mandate. The communication of critical audit matters will inform investors and other financial statement users of matters arising from the audit that involved especially challenging, subjective, or complex auditor judgment, and how the auditor addressed those matters.

Critical audit matters are determined using a principles-based framework and the Board anticipates that the level of auditor effort will depend on the nature and complexity of the audit. This would in turn depend on the complexity of the operations and accounting and control systems of the company.

Determination of Critical Audit Matters

Definition of Critical Audit Matter

The repropoed standard defined a critical audit matter as any matter arising from the audit of the financial statements that was *communicated or required to be communicated to the audit committee* and that *relates to accounts or disclosures that are material to the financial statements and involved especially challenging, subjective, or complex auditor judgment*. For the reasons explained below, the Board is adopting the definition as repropoed.

Communicated or Required To Be Communicated to the Audit Committee

Most commenters agreed that matters communicated or required to be communicated to the audit committee would be the appropriate source for critical audit matters. These

commenters stated that matters communicated to the audit committee are the most meaningful to users of the financial statements and using them as the source of critical audit matters would assist the auditor in determining critical audit matters in the most efficient and effective manner.

PCAOB standards require the auditor to communicate to the audit committee, among other things:

- Significant risks identified by the auditor;
- Certain matters regarding the company's accounting policies, practices, and estimates;
- Significant unusual transactions;
- Certain matters regarding the auditor's evaluation of the company's relationships and transactions with related parties; and
- Other matters arising from the audit that are significant to the oversight of the company's financial reporting process.

Several commenters suggested revising the source of critical audit matters. Some suggested narrowing the source of critical audit matters only to matters required to be communicated to the audit committee, on the basis that this would avoid chilling communications regarding non-required matters and reduce the burden of documentation. Other commenters suggested that the Board consider, as an alternative, selecting critical audit matters only from critical accounting policies and estimates disclosed by management, which some said would eliminate the potential for the auditor to become the original source of information, as well as the potential for conflicting disclosures between the auditor and management. Some commenters also recommended not specifying the source for critical audit matters and leaving it up to auditor judgment. Other commenters suggested broadening the source of critical audit matters to include matters documented in the engagement completion document, reviewed by the engagement quality reviewer, or communicated with management and other members of the board of directors, as the Board had originally proposed in 2013.

The final standard retains the source of critical audit matters as repropoed. Critical audit matters will be drawn from matters required to be communicated to the audit committee (even if not actually communicated) and matters actually communicated (even if not required). The source will include auditor communication requirements under AS 1301, *Communications with Audit Committees*, other PCAOB rules

and standards,⁴ and applicable law,⁵ as well as communications made to the audit committee that were not required. This approach scopes in the broadest population of audit committee communications and will not require the auditor to determine whether matters communicated to the audit committee were required to be communicated. However, it seems likely that matters that meet the definition of a critical audit matter will usually relate to areas that are required to be communicated to the audit committee, either under a specific communication requirement or the broad provisions of paragraph .24 of AS 1301, which requires communication of matters arising from the audit that are significant to audit committee oversight of the financial reporting process.

Required communications to the audit committee generally include the areas in which investors have expressed particular interest in obtaining information in the auditor's report, such as significant management estimates and judgments made in preparing the financial statements; areas of high financial statement and audit risk; significant unusual transactions; and other significant changes in the financial statements.

The final standard does not limit the source of critical audit matters to critical accounting policies and estimates because the Board does not believe this would be an appropriate starting point in light of investor interest in a broader range of topics related to the audit. Additionally, the final standard does not broaden the source, as proposed in 2013, to also include matters documented in the engagement completion document and reviewed by the engagement quality reviewer because it is unlikely that a matter that is determined to be a critical audit matter would not have already been communicated to the audit committee.

Some commenters suggested that using audit committee communications as the source for critical audit matters could impair the relationship between auditor, management, and the audit committee (e.g., chill communications, give rise to conflict, or cause auditors to communicate more than they otherwise would). However, other commenters argued that critical audit matters would

⁴ See Appendix B of AS 1301, which identifies other PCAOB rules and standards that require audit committee communication, such as AS 2410, *Related Parties*, and AS 2502, *Auditing Fair Value Measurements and Disclosures*.

⁵ See, e.g., Section 10A(k) of the Exchange Act, 15 U.S.C. 78j-1(k); Rule 2-07 of Regulation S-X, 17 CFR 210.2-07; and Exchange Act Rule 10A-3, 17 CFR 240.10A-3.

enhance, not impair, communications between auditors, investors, and those charged with governance (including audit committees). For matters required to be communicated to the audit committee, the Board believes there should not be a chilling effect or reduced communications to the audit committee because the requirements for such communications are not changing. It would seem that any chilling effect would more likely relate to matters that are not explicitly required to be communicated to the audit committee, although given the broad requirements of AS 1301 (particularly paragraph .24), the Board believes that there may be few, if any, relevant communications affected by that possibility.

Some commenters suggested excluding certain required audit committee communications from the source of critical audit matters, generally because these communications relate to sensitive areas and may result in the auditor communicating information not disclosed by management. Suggestions included: Corrected and uncorrected misstatements, qualitative aspects of significant accounting policies and practices, alternative treatments within generally accepted accounting principles (“GAAP”) for policies and practices related to material accounts, violations or possible violations of law or regulation, independence considerations, disagreements with management, other material written communications between the auditor and management, overall planned audit strategy, delays encountered in the audit, and competency issues of management. Other commenters argued that no audit committee communications should be specifically excluded from consideration as a source of potential critical audit matters.

The final standard does not exclude any required audit committee communications from the source of critical audit matters. To the extent that any such communication met the critical audit matter definition (including that it (1) relates to accounts or disclosures that are material to the financial statements and (2) involved especially challenging, subjective, or complex auditor judgment), the Board believes it will be an appropriate subject for an auditor to communicate as a critical audit matter.

Relates to Accounts or Disclosures That Are Material to the Financial Statements

The materiality component of the reproposed definition of critical audit matters—that the matter “relates to accounts or disclosures that are

material⁶ to the financial statements”—was intended to respond to investor requests for informative and relevant auditor’s reports while, at the same time, addressing other commenters’ concerns regarding auditor communication of immaterial information that management is not required to disclose under the applicable financial reporting framework and SEC reporting requirements.

Some investor commenters suggested removing the materiality component of the reproposed definition of critical audit matters, arguing that it made the definition too narrow and would unnecessarily exclude relevant information. Some of these commenters observed that many cases of material accounting problems or fraud started as “immaterial” to the financial statements and built over time, and that such matters may not meet the reproposed definition of a critical audit matter because of the materiality component.

Other commenters, primarily companies and accounting firms, argued that the reproposed definition was too broad and suggested modifying the materiality component such that a critical audit matter would itself have to be material to the financial statements as a whole, rather than relating to accounts or disclosures that are material to the financial statements. These commenters expressed concern that the phrase “relates to accounts or disclosures that are material to the financial statements” could apply to too many matters, resulting in the auditor disclosing immaterial matters that would not otherwise be disclosed by management, or give the impression of a piecemeal opinion.

After consideration of comments, the Board has determined to adopt the materiality component in the final definition of critical audit matter as reproposed. In the Board’s view, the purpose of the standard—making the auditor’s report more useful and informative to investors—is better served by auditor communication of matters related to accounts or

disclosures that are material to the financial statements. As one commenter noted, limiting the source of critical audit matters and adding a materiality component that directly relates to accounts and disclosures “would allow the auditor to emphasize the most important matters to users of the financial statements, and limit the inclusion of an overabundance of [critical audit matters] within the auditor’s report that could deemphasize their importance.”⁷

At the same time, in the Board’s view, limiting critical audit matters to those that are, in and of themselves, material to the financial statements as a whole would not serve the intended purpose of the standard. If the auditor were required to determine that a critical audit matter itself is material, rather than related to an account or disclosure that is material, it is likely that fewer matters would meet the definition of a critical audit matter and, thus, investors would likely receive less, and less audit-specific, information than under the standard as adopted.

Accordingly, as in the reproposal, the final standard provides that each critical audit matter relates to accounts or disclosures that are material to the financial statements. Consistent with the reproposal, “relates to” clarifies that the critical audit matter could be a component of a material account or disclosure and does not necessarily need to correspond to the entire account or disclosure in the financial statements. For example, the auditor’s evaluation of the company’s goodwill impairment assessment could be a critical audit matter if goodwill was material to the financial statements, even if there was no impairment; it would relate to goodwill recorded on the balance sheet and the disclosure in the notes to the financial statements about the company’s impairment policy and goodwill. In addition, a critical audit matter may not necessarily relate to a single account or disclosure but could have a pervasive effect on the financial statements if it relates to many accounts or disclosures. For example, the auditor’s evaluation of the company’s ability to continue as a going concern could also represent a critical audit matter depending on the circumstances of a particular audit.

On the other hand, a matter that does not relate to accounts or disclosures that are material to the financial statements

⁶ The definition of materiality is established under the U.S. federal securities laws. In interpreting those laws, the U.S. Supreme Court has held that a fact is material if there is “a substantial likelihood that the . . . fact would have been viewed by the reasonable investor as having significantly altered the ‘total mix’ of information made available.” See *TSC Industries v. Northway, Inc.*, 426 U.S. 438, 449 (1976). See also *Basic, Inc. v. Levinson*, 485 U.S. 224, 231–32 (1988). As the Supreme Court has further explained, determinations of materiality require “delicate assessments of the inferences a ‘reasonable shareholder’ would draw from a given set of facts and the significance of those inferences to him . . .” *TSC Industries*, 426 U.S. at 450.

⁷ See letter from Dixon Hughes Goodman, LLP (Aug. 15, 2016) at 2, available on the Board’s Web site in Docket 034 (also noting that there is a continuing risk that the auditor could disclose information about the company that was not previously disclosed by the company).

cannot be a critical audit matter. For example, a potential loss contingency that was communicated to the audit committee, but that was determined to be remote and was not recorded in the financial statements or otherwise disclosed under the applicable financial reporting framework, would not meet the definition of a critical audit matter; it does not relate to an account or disclosure in the financial statements, even if it involved especially challenging auditor judgment. The same rationale would apply to a potential illegal act if an appropriate determination had been made that no disclosure of it was required in the financial statements; the matter would not relate to an account or disclosure that is material to the financial statements.

For the same reason, the determination that there is a significant deficiency in internal control over financial reporting, in and of itself, cannot be a critical audit matter; such determination, in and of itself, does not relate to an account or disclosure that is material to the financial statements as no disclosure of the determination is required. A significant deficiency could, however, be among the principal considerations that led the auditor to determine that a matter is a critical audit matter.⁸

Involved Especially Challenging, Subjective, or Complex Auditor Judgment

Many commenters supported including “matters that involved especially challenging, subjective, or complex auditor judgment” in the repropoed definition of a critical audit matter. Other commenters argued that the phrase “especially challenging, subjective, or complex auditor judgment” is broad and subjective and would lead to inconsistent application of the repropoed definition. For example, some commenters said that critical audit matters would vary based on the experience and competence of the auditor, even if the underlying facts and circumstances were the same. One commenter urged disclosure of the auditor’s perspective on material related party transactions. Another commenter suggested that the standard include a note stating that it is expected that in most audits, financial statement matters involving the application of significant judgment or estimation by management would involve especially challenging, subjective, or complex auditor judgment.

Several commenters suggested using the IAASB’s definition of key audit matters, which includes those matters that were of most significance in the audit of the financial statements and that required significant auditor attention. One commenter argued that this would avoid reliance on the auditor’s determination of whether a matter involved especially challenging, subjective, or complex auditor judgment, which the commenter said would give auditors too much discretion.

After consideration of comments, the Board is adopting this component of the definition of critical audit matter as repropoed, namely “matters that involved especially challenging, subjective, or complex auditor judgment.” This grounds the definition in the auditor’s expertise and judgment, which is directly responsive to investor requests for information from the auditor’s point of view. Thus, the Board believes that this definition will focus critical audit matters in areas where investors will particularly benefit from expanded reporting by the auditor.

The determination of critical audit matters is principles-based and the final standard does not specify any items that would always constitute critical audit matters. For example, the standard does not provide that all matters determined to be “significant risks” under PCAOB standards would be critical audit matters.⁹ Some significant risks may be determined to be critical audit matters, but not every significant risk would involve especially challenging, subjective, or complex auditor judgment. To illustrate, improper revenue recognition is a presumed fraud risk and all fraud risks are significant risks;¹⁰ however, if a matter related to revenue recognition does not involve especially challenging, subjective, or complex auditor judgment, it will not be a critical audit matter. Similarly, the final standard does not provide, as some commenters suggested, that material related party transactions or matters involving the application of significant judgment or estimation by management always constitute critical audit matters. The auditor must determine, in the context of the specific audit, that a matter involved especially challenging, subjective, or complex auditor judgment. In addition, focusing on auditor judgment should limit the extent to which expanded auditor

reporting could become duplicative of management’s reporting. To the extent that critical audit matters reflect differences in auditors’ experience and competence, this in itself should also be informative.

Factors

The repropoal included the following nonexclusive list of factors for the auditor to take into account, together with audit-specific factors, when determining whether a matter involved especially challenging, subjective, or complex auditor judgment:

- a. The auditor’s assessment of the risks of material misstatement, including significant risks;
- b. The degree of auditor subjectivity in determining or applying audit procedures to address the matter or in evaluating the results of those procedures;
- c. The nature and extent of audit effort required to address the matter, including the extent of specialized skill or knowledge needed or the nature of consultations outside the engagement team regarding the matter;
- d. The degree of auditor judgment related to areas in the financial statements that involved the application of significant judgment or estimation by management, including estimates with significant measurement uncertainty;
- e. The nature and timing of significant unusual transactions and the extent of audit effort and judgment related to these transactions; and
- f. The nature of audit evidence obtained regarding the matter.

Commenters in general agreed that including such factors would assist the auditor in determining critical audit matters.

Some commenters suggested changes to better align the factors with areas of complex management judgment, to reduce the risk that the auditor would be the source of original information, to clarify the linkage of procedures performed by the auditor and sufficient appropriate audit evidence obtained in performing those procedures, and to focus the auditor on the audit procedures executed to obtain sufficient and appropriate audit evidence rather than audit strategy decisions. Some commenters suggested harmonizing the factors with the IAASB’s factors for determining key audit matters.

After considering the comments received, the Board has modified the factors by reordering them and revising the factor relating to the degree of auditor subjectivity (factor b above) to refer to the application (rather than determination) of audit procedures, which focuses it more clearly on the

⁸ See below for additional considerations related to auditor disclosure of original information.

⁹ A significant risk is a “risk of material misstatement that requires special audit consideration.” Paragraph .A5 of AS 2110, *Identifying and Assessing Risks of Material Misstatement*.

¹⁰ See AS 2110.71.

performance of the audit rather than audit strategy.

Some commenters suggested that the factor pertaining to the nature and extent of the audit effort (factor c) be revised to relate to the nature and extent of audit effort required to obtain sufficient appropriate audit evidence to address a matter and the factor pertaining to the nature of audit evidence (factor f) be deleted to clarify that obtaining audit evidence is a component of audit effort. The final standard does not change factor c as suggested because it would inappropriately narrow the factor exclusively to considerations related to obtaining audit evidence rather than the nature of the overall audit effort. Additionally, the Board determined to retain factor f as a stand-alone factor because, as stated in the reproposal, in the limited implementation trial conducted by several accounting firms, this factor appeared to be one of the most useful in determining critical audit matters.¹¹

A commenter recommended including a factor based on the extent of interaction with the audit committee. The final standard does not include this factor because the extent of interaction might not be a meaningful indicator of the complexity or subjectivity of the matter and it could create incentives to limit communication between the auditor and the audit committee.

One commenter did not agree with elimination of two proposed factors that related to the severity of control deficiencies and corrected and uncorrected misstatements. These factors were eliminated from the reproposal in response to comments that the factors would lead the auditor to determine matters as critical audit matters in areas where the company has no existing reporting obligation, or where the company has determined that the matters are not material and therefore do not require disclosure under the financial reporting framework. For these reasons, the final standard does not include these factors.

Under the final standard, once the auditor identifies a matter communicated or required to be communicated to the audit committee that relates to accounts or disclosures that are material to the company's financial statements, the auditor should take into account the following nonexclusive list of factors, as well as other audit-specific factors, when determining whether a matter involved

especially challenging, subjective, or complex auditor judgment:

- a. The auditor's assessment of the risks of material misstatement, including significant risks;
- b. The degree of auditor judgment related to areas in the financial statements that involved the application of significant judgment or estimation by management, including estimates with significant measurement uncertainty;
- c. The nature and timing of significant unusual transactions and the extent of audit effort and judgment related to these transactions;
- d. The degree of auditor subjectivity in applying audit procedures to address the matter or in evaluating the results of those procedures;
- e. The nature and extent of audit effort required to address the matter, including the extent of specialized skill or knowledge needed or the nature of consultations outside the engagement team regarding the matter; and
- f. The nature of audit evidence obtained regarding the matter.

The determination should be made in the context of the particular audit, with the aim of providing audit-specific information rather than a discussion of generic risks. The factors provide a principles-based framework for the auditor to use in assessing whether a matter involved especially challenging, subjective, or complex auditor judgment. Depending on the matter, the auditor's determination that a matter is a critical audit matter might be based on one or more of these factors, other factors specific to the audit, or a combination.

Audit Period Covered by Critical Audit Matters

The reproposal would have required the auditor to communicate critical audit matters for the audit of the current period's financial statements. Because the communication of critical audit matters for prior periods might also be useful to investors and other financial statement users in certain situations, the repropose standard provided that the auditor may communicate critical audit matters relating to a prior period when: (1) The prior period's financial statements are made public for the first time, such as in an initial public offering, or (2) issuing an auditor's report on the prior period's financial statements because the previously issued auditor's report could no longer be relied upon.

Some commenters generally supported communicating critical audit matters for only the current period's financial statements or for all periods if audited financial statements have not

been made public previously. Other commenters supported communication of critical audit matters for all periods presented along with an explanation if prior year critical audit matters are not repeated in the current year. Yet another commenter stated that the auditor should be encouraged to use judgment as to whether to include critical audit matters for prior periods and not limit the consideration only to the circumstances described in the reproposal.

The final standard retains the requirement to communicate critical audit matters only for the current audit period. While most companies' financial statements are presented on a comparative basis, and thus most auditor's reports cover a similar period, requiring auditors to communicate critical audit matters for the current period, rather than for all periods presented, will provide relevant information about the most recent audit and is intended to reflect a cost-sensitive approach to auditor reporting. In addition, investors and other financial statement users will be able to look at prior years' filings to analyze critical audit matters over time. However, the auditor could choose to include critical audit matters for prior periods. The final standard clarifies that the two situations relating to a prior period are examples rather than the only situations in which a critical audit matter for a prior period may be communicated.

As noted in the reproposal, if the auditor's report is dual-dated, the auditor will determine whether the new information for which the auditor's report is dual-dated gives rise to any additional critical audit matters.

In situations in which a predecessor auditor has been asked to reissue its auditor's report, the communication of critical audit matters for the prior period need not be repeated because it is only required for the current year. However, the predecessor auditor could choose to include prior year critical audit matters in the reissued auditor's report.

Requirements of Other Regulators and Standard Setters

IAASB. Under the IAASB's standard, "key audit matters" are defined as those matters that, in the auditor's professional judgment, were of most significance in the audit of the financial statements of the current period. Key audit matters are determined using a two-step process. First, the auditor identifies the matters communicated

¹¹ See letter from the Center for Audit Quality (June 19, 2014) at 5, available on the Board's Web site in Docket 034.

with those charged with governance¹² that required significant auditor attention in performing the audit, taking into account:

- Areas of higher assessed risks of material misstatement, or significant risks;
- Significant auditor judgments relating to areas in the financial statements that involved significant management judgment, including accounting estimates that have been identified as having high estimation uncertainty; and
- The effect on the audit of significant events or transactions that occurred during the period.¹³

Second, of the matters that required significant auditor attention, the auditor identifies those of most significance in the audit as the key audit matters.¹⁴ The IAASB requires the communication of key audit matters for the current period only.¹⁵

European Union (“EU”). The EU requires the auditor to describe the most significant assessed risks of material misstatement, including assessed risks of material misstatement due to fraud.¹⁶ The EU does not specify the period for which these need to be described.

Financial Reporting Council in the United Kingdom (“FRC”). The FRC requires the auditor to describe the risks of material misstatement that had the greatest effect on: (1) The overall audit strategy; (2) the allocation of resources in the audit; and (3) directing the efforts of the engagement team.¹⁷ The FRC does not specify the period for which these need to be described.

Communication of Critical Audit Matters

Under the reproposal, the auditor would have been required to include introductory language in the auditor's report preceding the communication of critical audit matters and to communicate critical audit matters by identifying each matter, describing the auditor's principal considerations for determining that the matter was a critical audit matter, describing how the critical audit matter was addressed in the audit, and referring to the relevant financial statement accounts and disclosures.

Comments varied on the repropose requirements for communication of critical audit matters and the level of detail the auditor should provide, including whether the auditor should be permitted to provide information about the company that has not been previously disclosed by the company (which commenters referred to as “original information”). Commenters generally agreed with identifying each critical audit matter and referring to the relevant financial statement accounts and disclosures. One commenter suggested removing the requirements to describe the considerations for determining that a matter was a critical audit matter and how the critical audit matter was addressed in the audit. While some commenters stated that the proposed requirements regarding auditor's communication of critical audit matters are sufficiently clear, many suggested improvements to some of the components of the communication requirements. After consideration of comments, the Board has made some enhancements to the communication requirements, as described below.

Introductory Language

The repropose standard provided introductory language to be included in the “Critical Audit Matters” section of the auditor's report indicating that critical audit matters did not alter the opinion on the financial statements and that the auditor was not providing a separate opinion on the critical audit matters. Some commenters supported the introductory language on the basis that it could minimize users' potential misunderstanding of the critical audit matters.

Some commenters suggested additions to the introductory language to emphasize that critical audit matters are subjective and may not represent the most important aspects of the financial statements, to clarify that the description of procedures should not be taken as indicative of results of any individual procedure, or to limit reliance on critical audit matters by adding language similar to that used in a report on an audit of internal control over financial reporting (“ICFR”).¹⁸ The

introductory language in the final standard does not include the suggested additions because such language could be interpreted as disclaiming or inappropriately minimizing the communication of critical audit matters.

Other commenters suggested minor revisions in the introductory language to refer to the “communication of critical audit matters” rather than the critical audit matters themselves. In response to this comment, the required introductory language in the final standard has been revised as follows (additions are *in italic* and deletions are in {brackets}):

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) Relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. *The communication of {C} critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we {do} are not, by communicating the critical audit matters below, {provide} providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.*

Communication Requirements

The reproposal required that, for each critical audit matter, the auditor would:

- Identify the critical audit matter;
- Describe the principal considerations that led the auditor to determine that the matter is a critical audit matter;
- Describe how the critical audit matter was addressed in the audit; and
- Refer to the relevant financial statement accounts and disclosures that relate to the critical audit matter.

As discussed in more detail below, these requirements have been adopted substantially as repropose.¹⁹

Control Over Financial Reporting That Is Integrated with An Audit of Financial Statements.

¹⁹ The repropose release included two illustrative examples of the communication of critical audit matters. See PCAOB Release No. 2016-003, Section IV.A.2.b. Given the principles-based nature of the requirements for critical audit matters and the objective of providing tailored, audit-specific information, the examples were intended to function as illustrations of how critical audit matters could be communicated, and not as templates for how critical audit matters should be communicated. Comments received on these examples were taken into account in the Board's consideration of the final standard. Illustrative examples do not appear in the adopting release because the Board believes auditors should provide tailored, audit-specific information when communicating critical audit matters in the auditor's report.

¹² See paragraph 8 of ISA 701. See also ISA 260, *Communication with Those Charged with Governance*, which provides requirements for auditor communications with those charged with governance.

¹³ See paragraph 9 of ISA 701.

¹⁴ See paragraph 10 of ISA 701.

¹⁵ See paragraphs 8 and 10 of ISA 701.

¹⁶ See requirements in 2(c) of Article 10, *Audit Report*, of Regulation (EU) No. 537/2014.

¹⁷ See paragraph 19A of UK ISA 700 (2013).

¹⁸ The auditor's report on the audit of internal control over financial reporting requires a paragraph stating that, “because of inherent limitations, internal control over financial reporting may not prevent or detect misstatements and that projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.” See paragraph .85j of AS 2201, *An Audit of Internal*

Identify the Critical Audit Matter and Describe the Principal Considerations That Led the Auditor To Determine That the Matter Is a Critical Audit Matter

Many commenters who addressed this topic supported the identification of the critical audit matter and limiting the description to “the principal considerations” that led the auditor to determine that the matter is a critical audit matter, and those aspects of the communication requirements are adopted as repropose. The auditor’s description of the principal considerations should be specific to the circumstances and provide a clear, concise, and understandable discussion of why the matter involved especially challenging, subjective, or complex auditor judgment. It is expected that the communication will be tailored to the audit to avoid standardized language and to reflect the specific circumstances of the matter.

Describe How the Critical Audit Matter Was Addressed in the Audit

The repropose standard included a new requirement for the auditor to describe how the critical audit matter was addressed in the audit. While the standard did not specify how this should be done, the repropose release provided four examples of potential approaches to such descriptions: (1) The auditor’s response or approach that was most relevant to the matter; (2) a brief overview of the procedures performed; (3) an indication of the outcome of the auditor’s procedures; and (4) key observations with respect to the matter, or some combination of these elements.²⁰

Many commenters were supportive of a requirement to describe how each critical audit matter was addressed in the audit. Some commenters asserted that a description of how a critical audit matter was addressed would benefit investors by providing insights on how and on what basis the auditor developed the opinion or the rigor that underlies the audit procedures performed. For example, one investor commenter stated that including audit procedures in the description of a critical audit matter would make the auditor’s report more informative and useful. Several investors suggested that the auditor should be required or encouraged to provide informative, company-specific findings when describing how the critical audit matter was addressed in

the audit, such as whether management’s significant accounting estimates and judgments were balanced, mildly optimistic, or mildly pessimistic.

One commenter suggested that the description of how the critical audit matter was addressed in the audit should be optional. Several commenters objected to the auditor including audit procedures in the description of critical audit matters because it would not provide any incremental value or actionable information to investors, investors may not have the expertise or context to understand audit procedures, or the description of audit procedures would become boilerplate. One commenter suggested adding a note to clarify that the purpose of describing audit procedures is to provide information about the audit but not specific details that would compromise the effectiveness of audit procedures. Other commenters suggested that only the principal audit procedures should be provided.

The final standard includes the requirement for the auditor to describe how the critical audit matter was addressed in the audit because it is consistent with the Board’s objective of providing more information about the audit and, if developed with an appropriate focus on the intended audience, should be of interest to users. Similar to the repropose, the final standard does not prescribe a specific way to meet this requirement. Several commenters suggested that the four examples provided in the repropose release be included in the standard because they provide helpful guidance on how the requirement could be met. The final standard includes a note incorporating these examples, which should clarify the Board’s expectations while providing flexibility in describing how a critical audit matter was addressed in the audit.

While the description of how the critical audit matter was addressed in the audit will require judgment, the auditor should bear in mind that the intent of communicating critical audit matters is to provide information about the audit of the company’s financial statements that will be useful to investors. A brief overview of the audit procedures performed is one of the alternatives for describing how the critical audit matter was addressed. If the auditor chooses to describe audit procedures, the descriptions are expected to be at a level that investors and other financial statement users would understand. In addition, as the four examples should make clear, the objective is to provide a useful summary, not to detail every aspect of

how the matter was addressed in the audit. Limiting the use of highly technical accounting and auditing terms in the description of critical audit matters, particularly if the auditor chooses to describe audit procedures, may help financial statement users better understand these matters in relation to the audit of the financial statements.

In its comment letter, a working group of the IAG stressed the importance to investors of auditor findings, which they described as “the one item that [they] believe would provide the greatest value to investors.”²¹ Acknowledging the difficulty of mandating reporting of findings, the working group recommended that the Board encourage auditors to include them voluntarily. Under the final standard, communication of the auditor’s findings is not required; however, in describing the audit response, the auditor may choose to include findings as an indication of the outcome of audit procedures or key observations about a matter. The Board shares the working group’s view that the inclusion of informative, company-specific audit findings related to critical audit matters may, in appropriate circumstances, be valuable to investors and encourages auditors to consider including such findings in their auditor’s reports. However, in describing findings, the language used should not imply that the auditor is providing a separate opinion on the critical audit matter or on the accounts or disclosures to which they relate.

Refer to the Relevant Financial Statement Accounts or Disclosures That Relate to the Critical Audit Matter

The repropose standard would have required the auditor to refer to the relevant financial statement accounts and disclosures that relate to the critical audit matter. There were few comments on this requirement. One commenter suggested that, to avoid duplication, reference should be made only to the disclosures and not the financial statement accounts. In response to this suggestion, the final standard clarifies that the auditor could refer to either the relevant account or disclosure, rather than both, to avoid potential duplication.

The repropose also solicited comment on whether, in addition to referring to the relevant financial

²⁰ These elements are similar to the IAASB’s elements described in paragraph A46 of ISA 701. The EU also requires that the auditor describe key observations with respect to the most significant assessed risks of material misstatement.

²¹ Letter from the IAG’s auditor’s report working group (Aug. 15, 2016) at 1, available on the Board’s Web site in Docket 034. The working group made a presentation regarding its comment letter at the IAG meeting in October 2016, available on the Board’s Web site.

statement accounts and disclosures, the auditor should refer to relevant disclosures outside the financial statements. Commenters that addressed this question generally opposed the auditor referencing disclosures outside the financial statements when describing a critical audit matter because it may incorrectly suggest that such information is audited or cause readers to misinterpret the auditor's role in relation to such information. The final standard only requires the auditor to refer to the relevant financial statement accounts or disclosures.

Additional Considerations Related to the Communication Requirements

Auditor Disclosure of "Original Information" About the Company

The repropoed standard included a note to indicate that, when describing critical audit matters in the auditor's report, the auditor is not expected to provide original information unless it is necessary to describe the principal considerations that led the auditor to determine that a matter is a critical audit matter or how the matter was addressed in the audit.

Investor commenters, including the auditor's report working group of the IAG, argued that there should not be any limitation on the auditor providing original information and that the reproposal went too far in constraining the auditor from providing original information in response to concerns expressed by other commenters (which were primarily companies and accounting firms).

Other commenters expressed the view that auditors should not provide original information about the company or should be limited to providing information about the audit and not the company. These commenters stated that the auditor providing original information about the company would be inconsistent with the traditional U.S. regulatory framework, whereby management provides information about the company and the auditor attests to compliance with the applicable financial reporting framework. However, one investor commenter noted that auditor reporting should not be limited by "original information," a term that is undefined in auditing literature.

No PCAOB standard, SEC rule, or other financial reporting requirement prohibits auditor reporting of information that management has not previously disclosed. Rather, there are areas under current law and auditing standards that require auditor reporting that goes beyond attesting to the

compliance of management disclosures (e.g., substantial doubt about a company's ability to continue as a going concern²² or illegal acts²³). As discussed in more detail below, auditors may have professional or state law obligations to maintain client confidentiality, but these obligations should not apply to, or should be preempted by, reporting obligations arising under federal law and regulations, including under PCAOB standards. Accordingly, the requirement to communicate critical audit matters is not, as some commenters have suggested, inconsistent with the existing U.S. financial reporting framework and auditors' other obligations.

Commenters also said that the role of the audit committee or management would be undermined by requiring the auditor to disclose information about the company's financial statements, since in their view it is solely management's responsibility to determine what disclosure is appropriate. Several commenters stated that the communication of critical audit matters would give auditors leverage to encourage disclosure of information by management, and that management would likely modify its disclosure in response to the communication of critical audit matters in the auditor's report so the auditor would not be a source of original information. While some commenters said that this would improve management disclosures, others said it would be an inappropriate expansion of the auditor's role or would add significant costs. Other commenters stated that companies could be harmed by the disclosure of confidential or competitively sensitive information. Another commenter expressed concern that investors could be confused or misled if auditor reporting lacked context or appeared to conflict with management disclosures. One commenter suggested that the auditor should disclose original information only if a disclosure matter continues to

be unresolved after discussion with management and the audit committee.

The Board acknowledges these concerns and, in developing the auditor's communication requirements, has sought to strike an appropriate balance between investor demands for expanded auditor reporting and the costs and potential unintended consequences associated with providing it. While auditor reporting of original information is not prohibited, it is limited to areas uniquely within the perspective of the auditor: Describing the principal considerations that led the auditor to determine that the matter is a critical audit matter and how the matter was addressed in the audit. The objective of critical audit matters—helping investors to focus on identified areas of the audit and understand how the auditor addressed them—may not be accomplished if the auditor is prohibited from providing such information. Moreover, prohibiting the auditor from providing such information could make critical audit matter communications incomplete in a way that could be confusing to or misunderstood by investors.

It seems likely, as one commenter observed, that auditors will generally not have incentives to provide information about the company that the company has not already made public. Another commenter noted that, in current practice, disclosure is already guided by an iterative process between management and the auditor, and expected that a similar process would occur for critical audit matters, reducing the likelihood that the auditor would be a source of original information since critical audit matters would likely overlap with increased management disclosure.²⁴ To the extent that an auditor's decision to communicate a critical audit matter incents the company to expand or supplement its own disclosure, the Board believes this may improve the quality of public disclosures, which would be an indirect benefit of the standard. However, if the company does not provide additional disclosure, and the information is necessary to describe the principal considerations that led the auditor to determine that the matter is a critical audit matter or how it was addressed in the audit, the Board believes it is in the public interest for the auditor to include that information in the auditor's report. The final standard therefore retains the note from the reproposal explaining that

²² See AS 2415, *Consideration of an Entity's Ability to Continue as a Going Concern*. The auditor is required to include a going concern explanatory paragraph if the auditor concludes that substantial doubt exists about the entity's ability to continue as a going concern for a reasonable period of time (see AS 2415.12). If management's disclosure with respect to the company's ability to continue as a going concern is inadequate, the auditor's reporting responsibility regarding going concern remains and the report includes either a qualified or an adverse opinion (see AS 2415.14).

²³ Auditors may be required, under certain circumstances, pursuant to the Private Securities Litigation Reform Act of 1995 (codified in Section 10A(b)1 of the Exchange Act), to make a report to the SEC relating to an illegal act that has a material effect on the financial statements.

²⁴ It should be noted, however, that critical audit matters are not a substitute for disclosures required of the company under the applicable financial reporting framework.

the auditor is not expected to provide information about the company that has not been made publicly available by the company unless such information is necessary to describe the principal considerations that led the auditor to determine that a matter is a critical audit matter or how the matter was addressed in the audit.

Of course, any matter that will be communicated as a critical audit matter will already have been discussed with the audit committee, and the auditor will be required to provide a draft of the auditor's report to the audit committee and discuss the draft with them.²⁵ In addition, as the auditor determines how best to comply with the communication requirements, the auditor could discuss with management and the audit committee the treatment of any sensitive information.

Some commenters also stated that, in areas where there are specific reporting obligations under the applicable financial reporting framework or SEC reporting requirements but the matter falls below the disclosure threshold (for example, a significant deficiency), auditor communication could, in effect, impose a lower disclosure threshold. With regard to such areas, it is likely that the nature of a critical audit matter and its description would be broader than, for instance, focusing on a significant deficiency. In addition, while the auditor is required to describe the principal considerations that led the auditor to determine that the matter is a critical audit matter, (which may include, if relevant, information about the company's processes and controls) and how the overall matter was addressed, it is not necessary for the auditor's description to use the terminology of the other auditing standard, such as "significant deficiency" within the broader context of a critical audit matter. For example, if a significant deficiency was among the principal considerations in determining that revenue recognition was a critical audit matter, the auditor would describe the relevant control-related issues over revenue recognition in the broader context of the critical audit matter without using the term "significant deficiency."²⁶

Some commenters suggested that any expanded disclosure requirements should come from the SEC and the Financial Accounting Standards Board ("FASB"), in the form of additional

management disclosures, rather than from the Board expanding requirements for auditor reporting. However, investors have consistently asked to hear more from the auditor, an independent third-party expert whose work is undertaken for the investor's benefit. As one commenter noted, the auditor is best suited to provide insights on how and on what basis the auditor developed its opinion. The final standard is designed to elicit information about the audit directly from the auditor's perspective.

If auditors can adequately convey to investors the principal considerations and how the auditor addressed the matter without including previously undisclosed information, it is expected that they will. However, the standard provides that even when management has not disclosed information, the auditor is not constrained from providing such information if it is necessary to describe the principal considerations that led the auditor to determine that a matter is a critical audit matter or how the matter was addressed in the audit.

The Board intends to monitor implementation of the critical audit matter requirements to determine if additional guidance is needed in this area.

Potential Compliance Issues Related to Critical Audit Matters

Some commenters suggested that the reporting of critical audit matters could create compliance challenges for companies.

Two commenters expressed concern that companies' SEC filings may have to be amended because of changes in the description or reporting of critical audit matters. In principle, auditors should approach errors and misstatements in the communication of critical audit matters in the same way they would approach any other error or misstatement in the auditor's report that does not affect the auditor's opinion or the ability of market participants to rely on the opinion.²⁷ It appears that under current practice, SEC filings have been amended solely to correct errors in auditor's reports, such as incorrect auditor's report dates or missing explanatory paragraphs.

Another commenter expressed concern that management may be asked to respond to investor questions regarding issues described in critical audit matters and may not be in a

position to do so, particularly in light of their responsibilities under Regulation FD. Given the auditor's responsibility to communicate with the audit committee, and the likelihood of extensive discussions between auditors and management regarding critical audit matters, it seems likely that management will be prepared to respond appropriately and in compliance with their legal obligations (including Regulation FD), as they would with regard to any other question about information included in an SEC filing.

Ability To Communicate No Critical Audit Matters

The reproposal provided that the auditor could determine there were no critical audit matters and provide a statement to that effect in the auditor's report. Commenters generally supported the auditor's ability to determine that there are no critical audit matters. Two commenters suggested that the auditor should not have to make a statement in the auditor's report that there were no critical audit matters because the absence of a critical audit matter should be sufficient without the definitive statement, similar to an emphasis paragraph. The final standard includes the possibility that the auditor could determine, and state in the auditor's report, that there are no critical audit matters.²⁸ The statement that there are no critical audit matters is required because unlike an emphasis paragraph, critical audit matters are a required element of the auditor's report.

The determination of critical audit matters is based on the facts and circumstances of each audit. The Board expects that, in most audits to which the requirement to communicate critical audit matters applies, the auditor will determine that at least one matter involved especially challenging, subjective, or complex auditor judgment. There may be critical audit matters even in an audit of a company with limited operations or activities. However, there may be circumstances in which the auditor determines there are no matters that meet the definition of a critical audit matter and, in those circumstances, the auditor will communicate that there were no critical audit matters.

²⁸ Since communication of critical audit matters will not be required for the audits of EGCs, brokers and dealers reporting under Exchange Act Rule 17a-5, 17 CFR 240.17a-5, investment companies other than business development companies, and benefit plans, the auditor's report for the audits of these entities will not be required to include the statement that there are no critical audit matters.

²⁵ See AS 1301.21, as amended.

²⁶ It should be noted that the determination that a matter was a significant deficiency in internal control over financial reporting, on its own, could not be a critical audit matter.

²⁷ The final standard indicates that the auditor's communication of critical audit matters does not alter in any way the auditor's opinion on the financial statements, taken as a whole.

Requirements of Other Regulators and Standard Setters

IAASB. For each key audit matter, the IAASB requires the auditor to reference the related disclosures, if any, in the financial statements and address: (1) Why the matter was considered to be one of most significance in the audit and therefore determined to be a key audit matter and (2) how the matter was addressed in the audit.²⁹ The IAASB allows the auditor to determine that there are no key audit matters to communicate in the auditor's report and, if so, requires a statement to this effect.³⁰

EU. The EU requires the auditor to include in the auditor's report: (1) A description of the most significant assessed risks of material misstatement, including assessed risks of material misstatement due to fraud; (2) a summary of the auditor's response to the risks; and (3) where relevant, key observations arising with respect to the risks.³¹

FRC. The FRC requires the auditor, among other things, to: (1) Describe those assessed risks of material misstatement that were identified by the auditor and (2) provide an overview of the scope of the audit, including an explanation of how the scope addressed the assessed risks of material misstatement.³² The explanations of the matters set out in the auditor's report should be described in a way that: (1) Enables a user to understand their significance in the context of the audit of the financial statements as a whole and not as discrete opinions on separate elements of the financial statements; (2) enables the matters to be related directly to the specific circumstances of the audited entity and are not therefore generic or abstract matters expressed in standardized language; and (3) complements the description of significant issues required to be made by the audit committee.³³

Documentation of Critical Audit Matters

The repropose standard required documentation of the basis for the auditor's determination whether each matter that both: (1) Was communicated or required to be communicated to the audit committee and (2) relates to accounts or disclosures that are material to the financial statements, involved or did not involve especially challenging, subjective, or complex auditor

judgment. Some commenters supported a documentation requirement only for matters that were determined to be critical audit matters. Some of these commenters asserted that documentation about matters determined not to be critical audit matters would add costs and primarily benefit PCAOB inspections rather than audit quality. Others stated that the requirement is not aligned with the IAASB's documentation requirement, which, in their view, focuses on rationale for inclusion as a key audit matter rather than exclusion. However, another commenter argued that the determination that a matter was not a critical audit matter would seem to be an important audit judgment that ought to be documented for review by the engagement quality reviewer. This commenter suggested that documentation be required only for matters required to be communicated to the audit committee (which would already have been documented) and not for those that are communicated otherwise. One auditor argued that the repropose requirement would lead auditors to document all audit committee communications even if not required, and that this would disproportionately affect smaller companies whose audit committees more commonly request information not required to be communicated under PCAOB standards.

The final standard substantially retains the approach from the reproposal of requiring the auditor to document the basis for determining critical audit matters.³⁴ The objective of the requirement is to document how the determination of critical audit matters (or the determination that there are no critical audit matters) was made from among the matters communicated or required to be communicated to the audit committee that relate to accounts or disclosures that are material to the financial statements. The documentation requirement will also facilitate review by the engagement quality reviewer.³⁵

The amount of documentation required could vary with the circumstances. For example, the auditor's basis for the determination

may be so clear for some matters that a single sentence will be sufficient. This situation may arise, for instance, when the auditor's documentation prepared in the course of the audit includes sufficient detail about whether or not the matter involved especially challenging, subjective, or complex auditor judgment. Other matters may require more extensive documentation.

As noted in the repropose release, for matters determined to be critical audit matters, the description in the auditor's report (which, among other things, must describe the principal considerations that led the auditor to determine that it was a critical audit matter) will generally suffice as documentation.

The auditor could comply with the documentation requirement in a variety of different ways. For example, the auditor could start with the communications to the audit committee, which are already documented, identify which of those matters relate to accounts or disclosures that are material to the financial statements, and then document the basis for the auditor's determination of whether or not each matter involved especially challenging, subjective, or complex auditor judgment. In documenting the basis for the determination, the auditor may include the factors the auditor took into account. This documentation may be prepared as an extension to the audit committee documentation or the auditor may prepare separate documentation.

Requirements of Other Regulators and Standard Setters

The IAASB requires the auditor to document the matters that required significant auditor attention and the rationale for the auditor's determination as to whether or not each of these matters is a key audit matter.³⁶ The EU does not include documentation requirements for expanded auditor reporting. The FRC does not include specific documentation requirements related to expanded auditor reporting.³⁷

Liability Considerations Related to Critical Audit Matters

In both the proposal and the reproposal, the Board acknowledged that including critical audit matters would change the auditor's report in ways that could affect auditors' potential liability. As discussed in those releases, liability may be imposed on auditors under a number of different legal theories depending on the specific

²⁹ See paragraph 13 of ISA 701.

³⁰ See paragraphs 14 and 16 of ISA 701.

³¹ See requirements in 2(c) of Article 10, Audit Report, of Regulation (EU) No. 537/2014.

³² See paragraph 19A of UK ISA 700 (2013).

³³ See paragraph 19B of UK ISA 700 (2013).

³⁴ The language of the documentation requirements has been redrafted to improve clarity, based on a commenter's suggestion.

³⁵ Under the existing audit documentation requirements, audit documentation facilitates the planning, performance, and supervision of the engagement, and is the basis for the review of the quality of the work because it provides the reviewer with written documentation of the evidence supporting the auditor's significant conclusions. See paragraph .02 of AS 1215, *Audit Documentation*.

³⁶ See paragraph 18(a) of ISA 701.

³⁷ General documentation requirements appear in ISA (UK and Ireland) 230, *Audit Documentation*.

facts and circumstances of a particular case, including pursuant to Section 11 of the Securities Act of 1933, Section 10(b) of the Exchange Act, and various state law causes of action. The critical audit matters would themselves be new statements that could be the basis for asserted claims. In addition, information provided regarding critical audit matters could affect other aspects of securities fraud claims against either the issuer, the auditor, or both (for example, by being described in pleadings in an effort to plead fraud with particularity or as a basis to seek to undercut a claim of reliance). The Board specifically sought comment on what effect the communication of critical audit matters would have on private liability and whether there were any steps the Board could or should take to address any likelihood of an increase in potential liability in private litigation.

A number of companies and accountants responded to this request for comment. While several of these commenters noted that changes from the proposal had addressed certain of their liability concerns, most continued to express varying degrees of concern about the potential for increased liability, either for auditors or for both auditors and companies.

In particular, commenters expressed concern that investors who suffer a financial loss could assert legal claims against the auditor based on statements made in identifying and describing critical audit matters. As with the proposal, commenters expressed general concerns that communication of critical audit matters would encourage baseless litigation, would likely lead to increased audit fees, raise the settlement value of spurious claims, or potentially undermine the stringent pleading standards of the Private Securities Litigation Reform Act of 1995, which were intended to curtail non-meritorious claims against auditors and avoid the costs and burdens associated with them. Some commenters argued that auditors, to avoid being second-guessed, would have the incentive to communicate matters to the audit committee that were not otherwise required or to identify too many critical audit matters in an effort to protect themselves from liability. Several commenters expressed concern that communicating critical audit matters might compromise their ability to argue that the statements in the audit report are opinions which, one commenter argued, were “less vulnerable to challenges that they are false or

misleading.”³⁸ However, at least one of these commenters noted that the revised definition of a critical audit matter in the reproposal mitigated their concern on that point. Other commenters argued that the information communicated in describing critical audit matters could potentially be used to attack the audit by challenging the procedures performed or the adequacy of audit evidence obtained by the auditor. On the other hand, one commenter noted that the communication of critical audit matters is about disclosure of risks and challenges and expressed the belief that non-communication of such matters would be more problematic from a litigation point of view.

Some commenters argued that the risk of liability would be heightened if the auditor were providing original information about the company. In particular, several commenters contended that doing so would conflict with accountants’ professional obligation to maintain client information in confidence, which could give rise to claims by the company against the auditor under state law.

Some commenters argued that critical audit matters could increase litigation risk for companies as well as the auditor because the new statements required of the auditor could form a basis for new legal claims, could be misinterpreted as acts of negligence on the part of the company, or could be used by plaintiffs as a “road map” for litigation against the company. One commenter argued that, because the underlying work papers are subject to discovery, critical audit matters would be used as a source for potential litigation against both auditors and companies.

Some of the commenters that expressed concerns about the potential for increased auditor liability also suggested changes to the reproposal that they maintained would reduce the liability impact of determining and communicating critical audit matters. For example, as previously discussed, several commenters suggested substantially similar changes to modify the materiality component of the definition of critical audit matters and to prohibit or discourage auditor communication of original information.

The Board has carefully considered commenters’ concerns about potential liability throughout this standard-setting process, including the comments received on the reproposal. While mandating disclosure of critical audit matters will, by design, entail new

statements in the auditor’s report, the Board notes that any claim based on these new statements would have to establish all of the elements of the relevant cause of action (for example, when applicable, loss causation and reliance). Critical audit matters will not replace or alter the fundamental requirement that the auditor’s report include the auditor’s opinion that the financial statements are fairly presented in accordance with the applicable financial reporting framework, which has been, and the Board expects will continue to be, the primary statement at issue in most private securities litigation under federal law involving auditors.

Throughout this standard-setting process, the Board has carefully considered commenters’ suggestions to alter the terms of its proposal to mitigate their concerns about potential liability for omitting a critical audit matter. As discussed in the reproposal, the Board limited and clarified the process for determining critical audit matters, including by narrowing the source of critical audit matters to matters communicated or required to be communicated to the audit committee, adding a materiality component to the critical audit matter definition, and refining the factors used to determine critical audit matters. Those changes, as well as the critical audit matter definition’s focus on the auditor’s judgment, should mitigate concerns about potential liability for omitting a critical audit matter. With respect to suggestions to further narrow the definition of critical audit matters and the related communication requirements, it is not clear, and commenters did not explain, how those changes would mitigate liability concerns other than by reducing the number and content of required communications of critical audit matters. As described above, the Board has determined not to incorporate those suggested changes because they appear likely to significantly reduce the number of potential critical audit matters and the informativeness of auditor communication of critical audit matters.

With respect to potential state law claims by companies against their auditors for disclosing original information, the Board notes that, as discussed above, it does not expect that, in general, critical audit matters will provide sensitive information that has not been disclosed by the company. With respect to the potential for a claim based on a situation in which the auditor found such disclosure necessary, the Board notes that auditors already have preexisting duties to

³⁸ Letter from PricewaterhouseCoopers LLP (Aug. 15, 2016) at 7, available on the Board’s Web site in Docket 034.

disclose original information in certain circumstances.³⁹ Commenters did not cite any specific examples in which these requirements have resulted in unwarranted claims against auditors for disclosing client confidences. Because the auditor's obligations under PCAOB standards arise under federal law and regulations, professional or state law duties of client confidentiality should not apply to,⁴⁰ or should be preempted by,⁴¹ the obligation to communicate critical audit matters.⁴²

While the Board takes seriously the prospect of potential increases in auditors' or companies' liability, the Board believes it has appropriately addressed commenters' concerns regarding liability in a manner compatible with the objectives of this rulemaking, and in view of the rulemaking's anticipated benefits. Indeed, the Board notes that at least one of the commenters that expressed concern about potential liability, noted that those concerns "should not stand in the way of moving forward" on the reproposed standard.⁴³ At the same time, the Board acknowledges that a

variety of claims can be raised related to the statements in the audit report and that litigation is inherently uncertain. If the final standard is approved by the SEC, the Board will monitor the standard after implementation for any unintended consequences.

Additional Improvements to the Auditor's Report

The reproposal provided a list of basic elements to be included in every auditor's report. Some of these basic elements, such as auditor tenure, would be new elements in the auditor's report. Other basic elements, such as the auditor's opinion, identification of the financial statements audited, and management's and auditor's responsibilities, were drawn from the existing auditor reporting standard.⁴⁴ Yet other basic elements, such as the name of the company under audit and the date of the financial statements, were incorporated from existing illustrative auditor's reports.

Auditor Tenure

The reproposal included a required statement in the auditor's report of the year the auditor began serving consecutively as the company's auditor. The Board also sought comment on whether auditor tenure should be disclosed in Form AP, *Auditor Reporting of Certain Audit Participants* ("Form AP"), rather than in the auditor's report.⁴⁵

Disclosure of Tenure

Investor commenters stated that information regarding auditor tenure would be useful to financial statement users, for example, in deciding whether to vote to ratify the appointment of the auditor. Investors that expressed a preference supported tenure disclosure in the auditor's report, some on the basis of reducing investor search costs by ensuring a consistent location for the disclosure. One commenter representing a group of investors asserted that since the auditor's report is the primary means by which the auditor communicates with investors, it is appropriate for auditor tenure to be included in the auditor's report. This commenter further stated that disclosure of auditor tenure on Form AP would be

an acceptable alternative to disclosure in the auditor's report only if the timeliness, accessibility, searchability, and overall functionality of the information disclosed on Form AP were at least equivalent to having the information disclosed in the auditor's report. Another commenter suggested that, if disclosure were required in the auditor's report, a specific location should be designated.

Currently, information about auditor tenure is not required to be communicated to investors by the auditor, management, or the audit committee.⁴⁶ However, there is a growing trend toward voluntary disclosure of auditor tenure. Recent analysis of corporate proxy statements for annual meetings of shareholders has found that a growing number of companies are disclosing auditor tenure,⁴⁷ presumably due to interest from investors. However, voluntary disclosure is not provided for a significant number of audits subject to the Board's jurisdiction. Additionally, if disclosed, such information may not be provided in the same location in the proxy statement; for instance, some disclosures are in the audit committee report while others are in another section of the proxy.⁴⁸ Further, the proxy rules do not apply to all companies required to be audited under PCAOB standards; for example, foreign private issuers, many companies whose

³⁹ For example, for at least the last 20 years, auditors have had duties to disclose in their auditor's reports when they have substantial doubt about the company's ability to continue as a going concern. See Section 10A of the Exchange Act and AS 2415. In addition, when in an audit of internal control over financial reporting, the auditor identifies a material weakness that has not been included in management's assessment, the auditor must modify its report to, among other things, "include a description of the material weakness, which should provide the users of the audit report with specific information about the nature of the material weakness and its actual and potential effect on the presentation of the company's financial statements . . .". See Note to paragraph .91 of AS 2201; cf. Statement of Gaylen R. Hansen, CPA, at the PCAOB public meeting (Apr. 2, 2014) ("Client confidentiality has a long-standing and important place in the accountancy profession. However, it doesn't serve investors well when it is parlayed to obfuscate the important obligation to call things as they are seen.").

⁴⁰ For example, the relevant AICPA rule provides that auditors "shall not disclose any confidential client information without the specific consent of the client," but further provides that the confidentiality obligation shall not be construed "to prohibit . . . compliance with applicable laws and government regulations." See paragraphs .01 and .02 of 1.700.001 *Confidential Client Information Rule* of the AICPA Code of Professional Conduct (as of Dec. 15, 2014).

⁴¹ See *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372–73 (2000); *New York v. FCC*, 486 U.S. 57, 64 (1988).

⁴² Some commenters suggested that safe harbor rules be created to protect auditors and companies from liability for statements about critical audit matters. While, as noted above, the Board will monitor the effects of critical audit matters should the requirements be approved by the SEC, the Board is not convinced at this time that any such safe harbor is necessary and, in any event, such a safe harbor is beyond the Board's authority.

⁴³ See letter from Deloitte & Touche LLP (Aug. 12, 2016) at 5, available on the Board's Web site in Docket 034.

⁴⁴ See existing AS 3101.06–.08.

⁴⁵ In December 2015, the Board adopted Form AP, which provides investors and other financial statement users with information about engagement partners and other accounting firms that participate in audits of issuers. See *Improving the Transparency of Audits: Rules to Require Disclosure of Certain Audit Participants on a New PCAOB Form and Related Amendments to Auditing Standards*, PCAOB Release No. 2015–008 (Dec. 15, 2015).

⁴⁶ In certain instances, investors may be able to manually calculate tenure by reviewing company filings on the SEC's Electronic Data Gathering, Analysis and Retrieval system ("EDGAR") to determine when a company changed auditors. However, the information is not available prior to 1994 and may not be available for certain entities, such as investment companies and brokers and dealers, that are not required to file Form 8–K. See 17 CFR 249.308, Item 4.01 *Changes in Registrant's Certifying Accountant*. Accordingly, currently available information is neither complete nor a readily accessible alternative to auditor tenure disclosure.

⁴⁷ The Center for Audit Quality, together with Audit Analytics, reviewed corporate proxies filed through the end of June 2016, 2015, and 2014 of 1,500 Standard and Poor's ("S&P") Composite companies. Their analysis identified that in 2016, 2015, and 2014 auditor tenure was disclosed in the annual proxy statements of 59, 54, and 47 percent of the S&P 500 large-cap companies, respectively, 45, 44, and 42 percent of the S&P MidCap 400 companies, respectively, and 48, 46, and 50 percent of the S&P SmallCap 600 companies, respectively. See Center for Audit Quality and Audit Analytics, *2016 Audit Committee Transparency Barometer* (Nov. 2016). Separately, during their review of proxy statements of Fortune 100 companies, Ernst & Young identified that 63 percent of the companies reviewed voluntarily disclosed auditor tenure in 2016 compared to 62 percent in 2015, 51 percent in 2014, 29 percent in 2013, and 24 percent in 2012. See Ernst & Young, *Audit Committee Reporting to Shareholders in 2016* (Sept. 2016).

⁴⁸ See Center for Audit Quality and Audit Analytics, *2016 Audit Committee Transparency Barometer* (Nov. 2016).

securities are not listed on a national securities exchange, and most investment companies are not required to prepare proxy statements.

Some commenters, primarily companies, did not support disclosure of auditor tenure in the auditor's report on the basis that such disclosure would not provide value to investors. Other companies and accounting firms raised a concern that tenure disclosure could result in inferences that, in their view, would be inappropriate about correlations between auditor tenure and audit quality, or between auditor tenure and auditor independence. Some commenters also suggested that auditor tenure is a corporate governance matter and that disclosure should be provided by management or the audit committee rather than the auditor. A few commenters suggested that tenure disclosure should be addressed by SEC rulemaking or provided only voluntarily. Some commenters, many of whom generally opposed auditor tenure disclosure, suggested that Form AP would be a preferable location for disclosing tenure if the Board proceeded with requiring the disclosure.

The SEC's Investor Advocate stated that he "strongly support[s] requirements for public disclosure of auditor tenure," recognizing that there were different opinions about the best party and location to make that disclosure.⁴⁹ Noting that the SEC had issued a concept release asking whether auditor tenure should be disclosed in the audit committee report,⁵⁰ the SEC's Investor Advocate stated that he believed the SEC should ultimately decide these questions. In light of these considerations, the SEC's Investor Advocate recommended that the PCAOB act to require disclosure of auditor tenure (either in the auditor's report or in Form AP), but also consider including a contingent sunset clause such that the auditor disclosure requirement would expire if and when the SEC imposed any form of a company disclosure requirement.

The Board believes that public disclosure of auditor tenure is important and in the public interest, and that it is

appropriate to require disclosure in the auditor's report because it is the primary means by which auditors communicate with investors. This will ensure that the disclosure is in a readily accessible and consistent location—the auditor's report—for all companies. It will make auditor tenure information immediately available to investors upon filing with the SEC of a document containing the auditor's report. Disclosure of auditor tenure in the auditor's report will also reduce search costs for investors who are interested in auditor tenure, relative to the current environment of voluntary reporting. Disclosure of auditor tenure in the auditor's report may also be more likely to encourage further discussion of auditor tenure by management and the audit committee and potential disclosure in company filings.

The Board is not persuaded by commenters' concerns that disclosure of auditor tenure in the auditor's report necessarily suggests a specific correlation between auditor tenure and audit quality, or between auditor tenure and auditor independence. In the Board's view, auditor tenure is another data point about the auditor, in addition to the firm name and the office issuing the auditor's report, for which there is demonstrable investor demand.

The standard does not specify a required location within the auditor's report for the statement on auditor tenure; auditors that are concerned about the inferences readers may draw based on the placement of the disclosure in the auditor's report have discretion to present auditor tenure in the part of the auditor's report they consider appropriate. Consistent with the reproposal, the illustrative auditor's report in the final standard includes the statement on auditor tenure at the end of the report.

The Board considered disclosure of auditor tenure in Form AP, which requires disclosure of the name of the engagement partner and of the names and percentage of participation of other accounting firms in the audit for all issuer audits. Form AP was developed primarily to respond to commenter concerns about the potential liability consequences of naming persons in the auditor's report, the potential need to obtain consents from those named persons in connection with registered securities offerings, and the additional time needed to compile information about the other accounting firms. The Board's determination to require disclosure in Form AP, rather than in the auditor's report, was a means to address these concerns. Disclosure of auditor tenure does not have the same potential liability or other consequences

as disclosure of the name of the engagement partner or other accounting firms, so such an approach is unnecessary in this case.

The Board acknowledges that the SEC, given its broader authority and responsibility for the financial reporting process, could in the future determine that auditor tenure should be disclosed by some other party or in some other location, in addition to or instead of in the auditor's report. Accordingly, the Board is adopting its requirement for tenure disclosure in the auditor's report today. The Board anticipates that, if the SEC undertook rulemaking for disclosure of auditor tenure, the Board would work with the SEC to ensure that PCAOB standards coordinate appropriately with any new SEC requirements.⁵¹

Determination of Tenure

The reproposal contemplated that tenure would be calculated taking into account firm or company mergers, acquisitions, or changes in ownership structure, and it included a note providing that if the auditor is uncertain as to the year the auditor became the company's auditor, the auditor should so state and provide the earliest year of which the auditor has knowledge. Some commenters objected to this approach, saying that it could confuse investors and its relevance is unclear. The Board believes that the disclosure of tenure should reflect the entire relationship between the company and the auditor, including the tenure of predecessor accounting firms and engagement by predecessors of the company under audit. No changes have been made to the note in the final standard.

Additionally, if a company went public and maintained the same auditor, auditor tenure will include the years the auditor served as the company's auditor both before and after the company became subject to SEC reporting requirements.

Because of the unique structure of investment companies, which typically includes common accounting, internal control, and oversight functions at the group level, the reproposed standard required that, for an investment company that is part of a group of investment companies,⁵² the auditor's

⁵¹ Of course, the SEC also has authority to abrogate or modify PCAOB rules at any time, to, among other things, further the purposes of the securities laws. Section 107(b)(5) of Sarbanes-Oxley, 15 U.S.C. 7217(b)(5).

⁵² A group of investment companies, as defined by Section 12(d)(1)(G)(ii) of the Investment Company Act of 1940 ("Investment Company Act"), means any two or more registered investment companies that hold themselves out to investors as

Continued

⁴⁹ See letter from Rick A. Fleming, Investor Advocate, SEC (Aug. 15, 2016) at 4, available on the Board's Web site in Docket 034. The letter noted that the views of the Investor Advocate do not necessarily reflect the views of the SEC, the Commissioners, or staff of the SEC, and the SEC disclaims responsibility for the letter and all analyses, findings, and conclusions contained therein. Additional information about the Office of the Investor Advocate is available on the SEC's Web site.

⁵⁰ See SEC, *Possible Revisions to Audit Committee Disclosures*, Exchange Act Release No. 75344 (July 1, 2015), 80 FR 38995 (July 8, 2015).

statement regarding tenure will contain the year the auditor began serving consecutively as the auditor of any investment company in the group of investment companies.⁵³ For example, if Firm A has been auditing investment companies in XYZ group of investment companies since 1980, the current auditor's report for XYZ fixed income fund, whose inception date was in 2010, will state that Firm A has served as the auditor of one or more XYZ investment companies since 1980.

A commenter asserted that measuring auditor tenure from the first year of service to the group of investment companies might confuse or even mislead the reader of the auditor's report for a new fund, especially if the auditor has served the group for several years. Another commenter supported the repropoed methodology for measuring tenure for investment companies stating that it is appropriate given the common accounting system, system of internal control over financial reporting, and board oversight for a group of investment companies.

After considering the comments received, the Board is adopting the requirement regarding auditor tenure for an investment company that is part of a group of investment companies as repropoed. The Board believes that the length of an auditor's relationship with the group is more relevant than the relationship with an individual fund, since funds can be started and merged over time but the auditor's relationship with the group continues.

Requirements of Other Regulators and Standard Setters

The EU requires a statement in the auditor's report that indicates the total uninterrupted engagement period, including previous renewals and reappointments of the statutory auditors or the audit firms.⁵⁴ The IAASB and the FRC do not include a similar requirement.

Clarification of Existing Auditor's Responsibilities

The repropoed standard included requirements that would enhance standardized language of the auditor's report by clarifying the nature and scope of the auditor's existing responsibilities,

related companies for purposes of investment and investor services. For purposes of determining auditor tenure, any tenure with other entities that may be part of an investment company complex, such as investment advisers or private investment companies, is not included.

⁵³ The following is an example of such statement: "We have served as the auditor of one or more [Group Name] investment companies since [year]."

⁵⁴ See requirements in 2(b) of Article 10, Audit Report, of Regulation (EU) No 537/2014.

such as a new statement regarding auditor independence and the addition of the phrase "whether due to error or fraud," when describing the auditor's responsibility under PCAOB standards to obtain reasonable assurance about whether the financial statements are free of material misstatements. In addition, the repropoed standard included a requirement intended to promote uniformity with respect to the addressee of the report.

Auditor Independence

The repropoed standard included a required statement in the auditor's report that the auditor is a public accounting firm registered with the PCAOB and is required to be independent with respect to the company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the SEC⁵⁵ and the PCAOB.⁵⁶

Commenters generally supported the required statement regarding auditor independence. Some said that the statement would reinforce financial statement users' understanding of the auditor's existing obligations to be independent and serve as a reminder to auditors of these obligations. Some commenters preferred a more definitive statement, such as stating that the auditor is in fact independent and in compliance with applicable independence rules. A few commenters questioned whether the statement will improve an investors' understanding of the auditor's independence responsibilities, yield any incremental benefits or insight to investors, or have any impact on auditor behavior. Some of these commenters pointed out that independence is already included in the title of the auditor's report and including an additional statement in the auditor's report is redundant and unnecessary.

After consideration of comments, the statement regarding auditor independence is adopted as repropoed. The Board believes that the independence statement in the auditor's report will both enhance investors' and other financial statement users' understanding of the auditor's existing obligations to be independent, and serve as a reminder to auditors of these obligations. The statement regarding auditor independence is not intended to, and will not, affect auditor independence requirements under the securities laws, SEC rules, or PCAOB rules.

⁵⁵ See Regulation S-X Rule 2-01, 17 CFR 210.2-01.

⁵⁶ See PCAOB Rule 3520, *et seq.*

Requirements of Other Regulators and Standard Setters

The IAASB requires that the auditor's report include a statement that the auditor is independent of the entity in accordance with the relevant ethical requirements relating to the audit and has fulfilled the auditor's other ethical responsibilities in accordance with these requirements.⁵⁷ The EU requires a statement in the auditor's report that the auditor remained independent of the audited entity in conducting the audit.⁵⁸ The FRC requires the auditor to state that the auditor is required to comply with the United Kingdom's ethical standards for auditors, which include requirements regarding auditor independence.⁵⁹

Addressee

Under the existing standard, the auditor's report may be addressed to the company whose financial statements are being audited, its board of directors, or stockholders.⁶⁰ Under current practice, the auditor's report is generally addressed to one or more of the following: (1) The board of directors and stockholders/shareholders, or their equivalent for issuers that are not organized as corporations; (2) the plan administrator or plan participants for benefit plans; and (3) the directors or equity owners for brokers or dealers.⁶¹

To promote consistency in addressing the auditor's report to the company's investors, the repropoed standard included a requirement for the auditor's report to be addressed to the shareholders and the board of directors, or equivalents for companies not organized as corporations. The repropoed standard stated that the auditor's report may include additional addressees.

Commenters generally supported the addressee requirement as repropoed stating that it is appropriate and will create consistency in practice. A commenter suggested limiting the required addressees to the shareowners of corporations or equivalents for companies not organized as corporations because investors are the key customers of the auditor's report. A few commenters stated that the auditor's report is intended for general use and the requirement for the auditor's report to be addressed to a specific party is not

⁵⁷ See paragraph 28(c) of ISA 700.

⁵⁸ See requirements in 2(f) of Article 10, *Audit Report*, of Regulation (EU) No 537/2014.

⁵⁹ See paragraph 15 of UK ISA 700 (2013).

⁶⁰ See existing AS 3101.09.

⁶¹ This information is based on a review by PCAOB staff of a random sample of 2014 fiscal year-end auditor's reports for issuers and brokers and dealers.

necessary. A commenter expressed concern that retaining the option for the auditor's report to be addressed to third parties could inadvertently result in increased auditor liability and cost.

In response to comments, and to promote greater uniformity in the addressees of the auditor's report, the Board is adopting the addressee requirement as repropoed. Since inclusion of additional addressees is voluntary, auditors could assess, based on the individual circumstances, whether or not to include additional addressees in the auditor's report. In addition, the Board believes that it is appropriate for the auditor's report to be addressed to the board of directors and not just to the shareholders, because of the role of the board of directors in the governance of the company.

Requirements of Other Regulators and Standard Setters

The IAASB requires that the auditor's report be addressed as appropriate, based on the circumstances of the engagement.⁶² The EU does not specify the addressee of the auditor's report. The FRC requires that the auditor's report be addressed as required by the circumstances of the engagement.⁶³ UK auditor's reports are typically addressed to either the members or the shareholders of the company.⁶⁴

Other Enhancements to the Basic Elements

The reproposal would have changed the language for certain elements in the existing auditor's report. These elements included:

- *Financial statement notes*—The identification of the financial statements, including the related notes and, if applicable, schedules, as part of the financial statements that were audited.⁶⁵ Under the existing standard, the notes to the financial statements and the related schedules are not identified as part of the financial statements.

⁶² See paragraph 22 of ISA 700.

⁶³ See paragraph 13 of UK ISA 700 (2013).

⁶⁴ See paragraph A5 of UK ISA 700 (2013).

⁶⁵ The final standard uses the term "financial statements" to include all notes to the statements and all related schedules, as used under SEC rules that apply to issuers. See Regulation S-X Section 1-01(b), 17 CFR 210.1-01(b), which states in part, "the term financial statements . . . shall be deemed to include all notes to the statements and all related schedules." The final standard will not apply to schedules included as supplemental information, as defined in AS 2701, *Auditing Supplemental Information Accompanying Audited Financial Statements*, because those schedules are not considered part of the financial statements. The auditor should continue to look to the requirements of AS 2701 for the auditor's reporting responsibilities regarding supplemental information accompanying audited financial statements.

- *Error or fraud*—A description of the auditor's responsibility to plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatements, whether caused by error or fraud.⁶⁶ The existing standard does not require the auditor's report to contain the phrase *whether due to error or fraud*.

- *Nature of the audit*—The description of the nature of the audit reflected the auditor's responsibilities in a risk-based audit and aligned the description with the language in the Board's risk assessment standards, including:

- Performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks;
- Examining, on a test basis, appropriate evidence regarding the amounts and disclosures in the financial statements;

- Evaluating the accounting principles used and significant estimates made by management; and
- Evaluating the overall presentation of the financial statements.

Commenters generally supported the repropoed language for these basic elements of the auditor's report. These elements are adopted as repropoed.

Additional Basic Elements Suggested by Commenters

In addition to the changes proposed by the Board, commenters on the reproposal suggested additional elements to be included in the auditor's report.

Several commenters suggested that the PCAOB consider additional standardized language in the auditor's report to describe the responsibilities of the auditor, management, and the audit committee. In doing so, some of these commenters suggested that the PCAOB consider additional language adopted by the IAASB, in order to promote consistency in reporting and to help users understand more fully the separate responsibilities of each of the parties with respect to the audited financial statements. In contrast, another commenter cautioned that a thorough description of everyone's roles and responsibilities would further add to repetitive boilerplate language. This commenter suggested instead that the auditor's report provide a cross reference to a more complete description of the roles and responsibilities of the auditor,

management, and the audit committee. This commenter did not indicate where such cross-referenced material would appear. Given little interest from investors in such additional language during the Board's initial outreach and the risk that it would be boilerplate, the final standard does not include these additional elements.

Two accounting firms suggested describing the meaning of reasonable assurance. The final standard requires a statement in the "Basis for Opinion" section of the auditor's report that the auditor "plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement." The auditing standards describe reasonable assurance as a high level of assurance, although not absolute assurance.⁶⁷ During the Board's initial outreach such additional language was considered, but there was no investor demand for it. As a result, the final standard does not expand the description of reasonable assurance in the auditor's report.

Some commenters also suggested that the auditor's report should include disclosure of the materiality measures used by auditors in planning the audit. These commenters asserted that it could help inform investors' proxy voting process for auditor ratification, as such disclosure could be a valuable supplement to an audit fee analysis and used to compare materiality over time to trends in restatements and adjustments. These commenters also observed that materiality disclosures are provided in the auditor's reports in the U.K. Other commenters from the Board's initial outreach stated that disclosing materiality levels in the auditor's report could have negative implications on audit quality by reducing the element of surprise necessary in an audit.⁶⁸ One commenter opposed a disclosure of materiality on the basis that it may encourage disclosure of quantitative materiality levels and ignore qualitative aspects of materiality, which cannot be described in a meaningful way in the auditor's report. The Board has decided not to include this additional element in the auditor's report at this time because disclosure may reduce the element of surprise in the audit and overstate the importance of quantitative rather than qualitative factors in the auditor's overall consideration of materiality. However, the Board will monitor the implementation of the final standard, as

⁶⁷ Paragraph .10 of AS 1015, *Due Professional Care in the Performance of Work*.

⁶⁸ See PCAOB Release No. 2011-003, Appendix C, for a detailed discussion of the staff's outreach regarding reporting materiality levels.

⁶⁶ See paragraph .02 of AS 1001, *Responsibilities and Functions of the Independent Auditor*.

well as the developments of expanded auditor reporting in other jurisdictions, to determine if future enhancements to the auditor's report may be warranted in this area.

Additionally, some commenters suggested that the auditor's report should define the auditor's responsibility for other information in documents containing audited financial statements so that financial statement users have a clear understanding. The Board's proposal included another new auditing standard, *The Auditor's Responsibilities Regarding Other Information in Certain Documents Containing Audited Financial Statements and the Related Auditor's Report*, regarding the auditor's responsibilities for other information outside the financial statements. The Board has not taken any further action since the proposal.

A few commenters suggested including other elements, such as the date when the auditor completed fieldwork, a statement that the auditor looked for material fraud, disclosure when alternative dispute resolution clauses are included in engagement letters, and disclosure of reasons for change in the engagement partner prior to mandatory rotation. The final standard does not include these elements because the Board believes they would not add meaningfully to the information already provided in the final standard or the elements go beyond what was considered in this standard-setting project and, thus, the Board is not including these elements at this time.

Explanatory Language and Emphasis of a Matter

Explanatory Language Required by Other PCAOB Standards

The repropose standard, similar to the existing standard,⁶⁹ provided a list of circumstances in which the auditor is required to add explanatory language to the auditor's report and included references to other PCAOB standards in which these circumstances and related reporting requirements are described. These circumstances included when there is substantial doubt about the company's ability to continue as a going concern and a restatement of previously issued financial statements, among others.

The list of circumstances from the Board's reproposal did not attract much comment, although one commenter affirmed support for including the list. Commenters on the Board's proposal

supported providing a list in the standard of the circumstances that require explanatory language in the auditor's report on the basis that keeping this information in a single place would facilitate consistency in execution. The final standard includes the list of explanatory paragraphs and related references as repropose.

The repropose standard included a requirement for the auditor to add explanatory language in cases where the company is required to report on ICFR but has determined that it is not required to obtain, and did not request the auditor to perform, an audit of ICFR.⁷⁰ The repropose standard included a reference to a new proposed requirement in AS 3105, *Departures from Unqualified Opinions and Other Reporting Circumstances*, for the auditor to add such explanatory language. Some commenters were supportive of the repropose requirement, while one commenter did not believe such a requirement was necessary but did not object to its inclusion.

The Board also sought comment on whether the requirement to include an explanatory paragraph in the auditor's report when the auditor did not perform an audit of ICFR should apply not only if company's management is required to report on ICFR, but also if management is not required to report, such as for investment companies. Several commenters supported expanding the requirement to all instances in which the auditor is not engaged to opine on ICFR, and not limit it to only when management is required to report on ICFR.

In the Board's view, it is appropriate to add explanatory language to the auditor's report when management has a reporting responsibility on ICFR but the auditor is not engaged to opine on ICFR, in order to clarify the auditor's responsibilities in this situation. For companies for which management is not required to report on ICFR, the Board does not believe that the auditor should have a separate reporting responsibility. Accordingly, the final standard retains the requirement as repropose.⁷¹ The auditor may, however, choose to

include such a paragraph in the auditor's report voluntarily.

Interaction between critical audit matters and explanatory paragraphs. The repropose standard clarified that critical audit matters are not a substitute for required explanatory paragraphs. However, there could be situations in which a matter meets the definition of a critical audit matter and also requires an explanatory paragraph, such as going concern. For these situations, the reproposal contemplated that both the explanatory paragraph and the required communication regarding the critical audit matter would be provided. The auditor could include the communication required for a critical audit matter in the explanatory paragraph, with a cross-reference in the critical audit matter section to the explanatory paragraph. Alternatively, the auditor could choose to provide both an explanatory paragraph and the critical audit matter communication separately in the auditor's report, with a cross-reference between the two sections.⁷² While the information reported in a critical audit matter may overlap with some of the information already provided in the explanatory paragraph, the critical audit matter would provide incremental information, such as how the matter was addressed in the audit.

Commenters were generally supportive of the interaction between the communication of critical audit matters and required explanatory paragraphs as described in the repropose standard. Some alternative views, however, were expressed. One commenter thought that if a required explanatory paragraph is also a critical audit matter, disclosure in the auditor's report should be limited to one place in the auditor's report. The commenter suggested that the communication requirements for both a critical audit matter and an explanatory paragraph be reported in the critical audit matter section of the auditor's report with a cross reference in the explanatory paragraph section. Another commenter suggested that the PCAOB harmonize its approach with that of the IAASB, which requires a reference in the key audit matter section but waives the requirements to describe the key audit matter and how it was addressed during the audit. Finally, another commenter thought that critical audit matter communications should not be

⁶⁹ This may be the case for companies that are subject to Section 404(a) of Sarbanes-Oxley, which mandates management ICFR reporting, but not Section 404(b), which mandates auditor ICFR reporting. Section 404(a) generally applies to companies that are subject to the reporting requirements of the Exchange Act, other than registered investment companies. Certain categories of companies that are subject to Section 404(a), such as nonaccelerated filers and emerging growth companies, are not subject to Section 404(b).

⁷¹ See amendments to AS 3105.59–.60.

⁷² When both an explanatory paragraph and a critical audit matter communication are provided, the critical audit matter description should not include conditional language that would not be permissible in the explanatory paragraph. See footnote 5 of AS 2415.

⁶⁹ See existing AS 3101.11.

permitted to be integrated with explanatory paragraphs, on the basis that explanatory paragraphs are about matters in the financial statements to which the auditor wants to draw the reader's attention and are not necessarily critical audit matters.

The final standard retains the interaction between critical audit matters and explanatory paragraphs as repropoed. The approach provides flexibility on auditor disclosure, yet also ensures that the communication requirements are met.

Emphasis of a Matter

The repropoed standard, similar to the existing standard, provided the ability for the auditor to add a paragraph to the auditor's report to emphasize a matter regarding the financial statements ("emphasis paragraph").⁷³ Emphasis paragraphs are not required, but may be used by auditors to draw the reader's attention to matters such as significant transactions with related parties and unusually important subsequent events.

The repropoed standard provided a list of potential matters that the auditor may emphasize in the auditor's report, although the auditor may also decide to emphasize other matters.

Commenters were supportive of emphasis paragraphs as described in the repropoed standard and did not suggest any additional matters to be included in the list of potential emphasis paragraphs. The final standard includes emphasis paragraphs as repropoed.

Interaction between critical audit matters and emphasis paragraphs. The repropoed standard stated that emphasis paragraphs are not a substitute for required critical audit matters. If a matter that the auditor considers emphasizing meets the definition of a critical audit matter, the auditor would provide the information required for critical audit matters, and would not be expected to include an emphasis paragraph in the auditor's report. Although this did not generate much comment, one commenter affirmed support for the interaction between critical audit matters and emphasis paragraphs. The final standard retains the interaction between critical audit matters and emphasis paragraphs as repropoed.

Requirements of Other Regulators and Standard Setters

Under the requirements of other regulators and standard setters, there are no analogous explanatory paragraphs, except for reporting on going concern.

The Board's repropoed approach is similar to the IAASB's approach to the interaction between a paragraph regarding the company's ability to continue as a going concern and key audit matters, although the underlying requirements for auditor reporting on going concern vary.⁷⁴ Under the IAASB's approach, an emphasis of matter paragraph is not required for a matter that was determined to be a key audit matter.⁷⁵ The EU and the FRC have separate requirements related to going concern reporting that do not specifically address the interaction with their expanded auditor reporting.⁷⁶ The IAASB, FRC, and EU do not have requirements for reporting on ICFR.

Information About Certain Audit Participants

On May 9, 2016, the SEC approved new rules and related amendments to the Board's auditing standards, including amendments to AS 3101, that will provide investors and other financial statement users with information about engagement partners and other accounting firms that participate in audits of issuers.⁷⁷ Firms will be required to file Form AP with the PCAOB for each issuer audit, disclosing this information. In addition to filing Form AP, firms will also have the choice to include this information in the auditor's report.⁷⁸ The final standard incorporates the adopted amendments to AS 3101 for situations in which the auditor decides to include information about certain audit participants in the auditor's report. The final standard requires the auditor to use an appropriate section title when providing this information in the auditor's report, but does not require a specific location in the auditor's report.

Requirements of Other Regulators and Standard Setters

The IAASB requires the auditor to include the name of the engagement partner in the auditor's report for audits of listed entities.⁷⁹ Under EU law, the engagement partner is required to sign

the audit report in all EU countries, including the United Kingdom.⁸⁰ Unlike disclosure of the engagement partner's name, disclosure of other accounting firms that participated in the audit is not required by the IAASB, FRC, or the EU.

Form of the Auditor's Report

The repropoed standard required the "Opinion on the Financial Statements" section to be the first section of the auditor's report, immediately followed by the "Basis for Opinion" section. The repropoed standard did not specify an order for the remaining sections of the auditor's report, which would include explanatory paragraphs and critical audit matters. This approach allowed for consistency in the location of the opinion and basis for opinion sections, with flexibility for the other elements of the auditor's report. The repropoed standard also required titles for all sections of the auditor's report to provide consistency and assist users in identifying the individual sections of the auditor's report.

Commenters were generally supportive of the proposed changes to the form of the auditor's report, because the changes will:

- Enhance the clarity and comparability of disclosures;
- Make it easier for investors to find the opinion since it will be listed first;
- Help facilitate a comparison between auditor's reports; and
- Allow for an appropriate level of flexibility and ease of use without being overly prescriptive.

Some commenters suggested the PCAOB should be consistent with other standard setters in the ordering of section titles in the auditor's report. One commenter expressed concern that the ordering of the components of the opinion and the heading of the critical audit matter section of the report may be misunderstood to imply that critical audit matter communications are separate and distinct from the auditor's opinion, which could be misinterpreted as a piecemeal opinion. In light of the commenter support described above, the Board is adopting the form of the auditor's report as repropoed. As previously discussed, the final standard includes revised introductory language in the auditor's report to avoid the potential misperception that the communication of critical audit matters provides piecemeal opinions.

⁷⁴ See paragraph A1 of ISA 570, *Going Concern*, and paragraph 15 of ISA 701.

⁷⁵ See paragraph 8 of ISA 706, *Emphasis of Matter Paragraphs and Other Matter Paragraphs in the Independent Auditor's Report*.

⁷⁶ See ISA (UK and Ireland) 570, *Going Concern*, and see Article 28, *Audit Reporting*, of Directive 2014/56/EU of the European Parliament and of the Council (Apr. 16, 2014).

⁷⁷ See PCAOB Release No. 2015-008.

⁷⁸ When the auditor divides responsibility for the audit under AS 1205, *Part of the Audit Performed by Other Independent Auditors*, the auditor's report must acknowledge the involvement of the other auditor.

⁷⁹ See paragraph 45 of ISA 700.

⁷³ See existing AS 3101.19.

⁸⁰ Directive 2006/43/EC of the European Parliament and of the Council, Article 28, *Audit Reporting* (May 17, 2006).

Requirements of Other Regulators and Standard Setters

The repropoed approach with respect to the order of the sections of the auditor's report is generally consistent with that of the IAASB.⁸¹ The EU and FRC do not specify an order to the auditor's report.

Application to Other Audits Performed Under PCAOB Standards

There are situations in which an auditor may be required by law or regulation, or voluntarily agrees, to perform an audit engagement in accordance with PCAOB standards for a company whose audit is not subject to PCAOB oversight.⁸² For example, SEC rules permit audits under PCAOB standards in connection with offerings under Regulation A and Regulation Crowdfunding.⁸³ In these situations, certain elements of the auditor's report required under the final standard, such as the use of "registered public accounting firm" in the title or the statement regarding independence requirements, may not apply. Additional guidance for these situations will be provided.

Amendments to Other PCAOB Standards

The Board has adopted amendments to several of its existing auditing standards solely to conform to the final standard. The Board is not adopting any further changes to these existing auditing standards at this time, although the Board recognizes that some of the existing auditing standards, such as the redesignated standard AS 3105, may need further updating. The Board may consider proposing further changes to these standards under separate standard-setting projects.

AS 3105, Departures From Unqualified Opinions and Other Reporting Circumstances

Existing AS 3101.10 and .20–.76 address departures from the auditor's unqualified opinion, such as a qualified opinion, an adverse opinion, or a

disclaimer of opinion, and other reporting circumstances, such as reporting on comparative financial statements. These paragraphs are redesignated as AS 3105.⁸⁴ Commenters who addressed this topic generally supported the repropoed amendments to AS 3105, including amending the example auditor's reports to conform with the example auditor's report in the final standard. The Board also received some comments suggesting further changes to AS 3105, such as updating descriptions of and references to accounting requirements that are no longer current⁸⁵ and updating certain terminology (e.g., changing references from "entity" to "company"). The Board may consider such updates as part of a separate standard-setting project.

The Board has adopted final amendments to AS 3105 that are substantially similar to the repropoal. The amendments to AS 3105 are not intended to change the circumstances in which the auditor would depart from an unqualified opinion. The changes from the current standard will primarily: (1) Require the communication of critical audit matters in certain circumstances; (2) revise certain terminology to align with the final standard; and (3) amend the illustrative reports for the basic elements of the final standard and the required order of certain sections of the auditor's report.

AS 3105 includes:

Communication of Critical Audit Matters in Reports Containing Other Than Unqualified Opinions

a. *Qualified opinion*—Amendments to AS 3105 will require that when the auditor expresses a qualified opinion, the auditor's report also include communication of critical audit matters, if critical audit matter requirements apply.

b. *Adverse opinion*—The existing requirements related to an adverse opinion are not amended to require the auditor to communicate critical audit matters. In the Board's view, the most important matter to investors and other financial statement users in such circumstances would be the reason for the adverse opinion.

c. *Disclaimer of opinion*—The existing requirements related to a disclaimer of an opinion are not amended to require the auditor to communicate critical audit matters. In the Board's view, the most important matter to investors and other financial statement users in such circumstances would be the reason for the disclaimer of opinion.

Requirements of Other Regulators and Standard Setters

Under the IAASB's approach, a matter giving rise to a qualified, adverse, or disclaimer of opinion is by nature a key audit matter.⁸⁶ However, in such circumstances: (1) The matter should not be described in the key audit matter section of the auditor's report, (2) the auditor should report on the matter in accordance with applicable standards, and (3) the auditor should include a reference in the key audit matter section to the basis for modified opinion section where the matter is reported.⁸⁷ The requirements to determine and communicate key audit matters, other than the matters giving rise to the modified opinion, would still apply when the auditor expresses a qualified or adverse opinion, but not when the auditor disclaims an opinion on the financial statements.⁸⁸ The FRC and the EU do not include specific requirements for expanded auditor reporting when the auditor's report contains other than an unqualified opinion.

Other Amendments to PCAOB Standards

The amendments to other PCAOB standards are substantially as repropoed. These include:

- AS 1220, *Engagement Quality Review*—amending to require the engagement quality reviewer to evaluate the engagement team's determination, communication, and documentation of critical audit matters;
- AS 1301, *Communications with Audit Committees*—amending to require the auditor to provide to and discuss with the audit committee a draft of the auditor's report;
- AS 2201, *An Audit of Internal Control Over Financial Reporting That Is Integrated with An Audit of Financial Statements*—amending the example auditor's report to conform with the example auditor's report on the financial statements in the final standard;
- AS 2820, *Evaluating Consistency of Financial Statements*—amending to

⁸⁶ See paragraph 15 of ISA 701.

⁸⁷ *Id.*

⁸⁸ See paragraph A7 of ISA 701 and paragraph 29 of ISA 705, *Modifications to the Opinion in the Independent Auditor's Report*.

⁸¹ See paragraphs 23–28 of ISA 700.

⁸² Under the Sarbanes-Oxley Act, as amended by the Dodd-Frank Wall Street Reform and Consumer Protection Act, the PCAOB oversees the audits of "issuers" and brokers and dealers reporting under Exchange Act Rule 17a–5. See Sarbanes-Oxley Act Section 101. An "issuer" under the Sarbanes-Oxley Act is an entity whose securities are registered under Section 12 of the Exchange Act, or that is required to file reports under Section 15(d) of the Exchange Act, or that files or has filed a Securities Act registration statement that has not yet become effective and that it has not withdrawn. See Sarbanes-Oxley Section 2(a).

⁸³ See Securities Act Form 1–A, Part F/S (b)(2) and (c)(1)(iii); Regulation Crowdfunding Rule 201(t) instruction 9, 17 CFR 227.201(t).

⁸⁴ AS 3101.01–.09 and .11–.19 are amended and restated as AS 3101, *The Auditor's Report on an Audit of Financial Statements When the Auditor Expresses an Unqualified Opinion*.

⁸⁵ The Board has issued guidance regarding the status of outdated descriptions of and references to U.S. GAAP in PCAOB standards. See PCAOB, *Staff Questions and Answers, References to Authoritative Accounting Guidance in PCAOB Standards* (Sept. 2, 2009). Among other things, this guidance provides that auditors should disregard descriptions of and references to accounting requirements in PCAOB standards that are inconsistent with the FASB Accounting Standards Codification ("ASC").

include the existing reporting requirements and illustrative explanatory language related to a change in accounting principle or a restatement that is currently in AS 3105; and

- AS 4105, *Reviews of Interim Financial Information*—amending to include the basic elements of the final standard, where applicable.

Conforming amendments were also made to every PCAOB standard that refers to the auditor's report. Commenters generally supported the amendments as repropoed.

A commenter suggested revising AS 3305, *Special Reports*, to conform to the example auditor's report in the final standard. Since reports pursuant to AS 3305 are rarely filed with the SEC, as noted by this commenter, the Board does not believe these reports should be updated at this time. As described above, the Board may consider updating this standard as part of a separate standard-setting project.

D. Economic Considerations and Application to Audits of Emerging Growth Companies

The Board is committed to analyzing the economic impacts of its standard setting. The following discussion addresses the potential economic impacts, including potential benefits and costs, considered by the Board. The Board has sought information relevant to economic consequences several times over the course of the rulemaking. Commenters provided views on a wide range of issues pertinent to economic considerations, including potential benefits and costs, but did not provide empirical data or quantified estimates of the costs or other potential impacts of the standard. The potential benefits and costs considered by the Board are inherently difficult to quantify, therefore the Board's economic discussion is primarily qualitative in nature.

Commenters who discussed the economic analysis in the Board's reproposal provided a wide range of views. Some commenters pointed to academic research for the Board to consider in support of their views. One commenter asserted that the Board's release did not provide a true economic analysis of the pros and cons of mandating the reporting of critical audit matters, but only referenced academic studies on the purported benefits of such reporting. Another argued that the changes described in the reproposal would lead to a significant increase in costs, and that no compelling case had been made that the benefits would exceed the costs. The SEC's Investor Advocate said that the Board's

economic analysis made a compelling case as to why the required reporting of critical audit matters would reduce informational asymmetries and add to the total mix of information available to investors.⁸⁹ The Board has considered all comments received and has sought to develop an economic analysis that evaluates the potential benefits and costs of the final standard, as well as facilitates comparisons to alternative Board actions.

Need for the Rulemaking

Critical Audit Matters

Generally, investors and other financial statement users know less about a company's financial performance than do others closer to the financial reporting process, particularly management. This information asymmetry⁹⁰ can result in situations where capital is allocated suboptimally. The system of financial reporting in the United States, which requires periodic reporting of information, including annual financial statements, helps address the information asymmetry between investors and management. Board of directors and audit committee oversight of the financial reporting process can further reduce this information asymmetry by enhancing the quality of the information disclosed to the public. As part of this system, the audit of the financial statements also helps reduce the information asymmetry investors face by providing an independent opinion about whether the financial statements are presented fairly in all material respects.

Companies' operations continue to become more complex and global. In addition, over the last decade, there have been changes in the financial reporting frameworks relating to accounting estimates and an increasing use of fair value as a measurement attribute, together with new related disclosure requirements.⁹¹ These estimates and fair value measurements, which are important to a financial statement user's understanding of the company's financial position and results of operations, can be highly subjective, require significant judgment, and can result in increased measurement uncertainty in financial statements.⁹²

⁸⁹ See letter from Rick A. Fleming, Investor Advocate, SEC (Aug. 15, 2016) at 3, available on the Board's Web site in Docket 034.

⁹⁰ Economists often describe "information asymmetry" as an imbalance, where one party has more or better information than another party.

⁹¹ See PCAOB Staff Consultation Paper, *Auditing Accounting Estimates and Fair Value Measurements* (Aug. 19, 2014).

⁹² See IAASB Project Proposal, Revision of ISA 540, *Auditing Accounting Estimates, Including Fair*

The increased complexity of financial reporting, including the growing use of complex accounting estimates and fair value measurements, may contribute to the information asymmetry between investors and management, despite the fact that management is required to provide significant disclosures to investors and other financial statement users. Some commenters on the reproposal have stated that investors would find information provided by the auditor, an independent third party, particularly relevant in this setting.

As part of the audit, auditors often perform procedures involving challenging, subjective, or complex judgments, such as evaluating calculations or models, the impact of unusual transactions, and areas of significant risk. Although the auditor is required to communicate with the audit committee regarding such matters, the auditor's report has not been expanded to provide this information to investors and generally provides only a standardized pass/fail opinion. Because the auditor's report generally does not contain audit-specific information, it provides very little of the information the auditor knows about the company, its financial reporting, and the challenges of the audit. Given the increased complexity of financial reporting, which requires the auditor to evaluate complex calculations or models and make challenging or subjective judgments, the current form of the auditor's report does little to address the information asymmetry between investors and auditors.

The Board believes that expanding the auditor's report to provide information about especially challenging, subjective, or complex auditor judgments will help investors and other financial statement users "consume" the information presented in management's financial statements more effectively. Stated in economic terms, in the Board's view, an expanded auditor's report will reduce the information asymmetry between investors and auditors, which should in turn reduce the information asymmetry between investors and management about the company's financial performance. Reducing information asymmetry about the company's financial reporting should lead to a more efficient allocation of capital.

Some commenters supported the reporting of critical audit matters as a means of reducing the information asymmetry between investors and auditors. Other commenters disagreed with the Board's approach and

questioned whether the Board could or should attempt to reduce information asymmetry by requiring expanded auditor reporting. The Board believes that requiring expanded auditor reporting as a means of reducing the information asymmetry between investors and auditors is consistent with its statutory mandate to “protect the interests of investors and further the public interest in the preparation of informative, accurate and independent audit reports.”⁹³ Investors are the intended beneficiaries of the audit, but investors do not receive information about specific work performed during the audit. The final standard seeks to enhance the form and content of the auditor’s report to make it more relevant and informative to investors and other financial statement users.

Increasing the Informativeness of the Auditor’s Report To Address Information Asymmetry

The communication of critical audit matters will reduce the information asymmetry between investors and auditors by informing investors and other financial statement users about areas of the audit that required especially challenging, subjective, or complex auditor judgment, including the principal considerations for determining the matters and how the matters were addressed in the audit. The Board believes that auditor reporting of critical audit matters will provide investors with audit-specific information that should facilitate their analysis of the financial statements and other related disclosures. The communication of critical audit matters in the auditor’s report should also help investors and analysts who are interested in doing so to engage management and the audit committee with targeted questions about these issues.⁹⁴ Ultimately, while not every critical audit matter will be useful for every investor, broadly, the Board believes that having the auditor provide investors and other financial statements users with additional information about especially challenging, subjective, or complex auditor judgments should help reduce the information asymmetry that exists between investors and management by providing additional insights on the financial statements.

The communication of critical audit matters should also assist investors in

assessing the credibility of the financial statements and, in at least some instances, audit quality.⁹⁵ For example, the description of how the auditor addressed the critical audit matter will help investors understand the types of issues that the auditor grappled with in addressing these challenging, subjective, or complex areas of the audit, which should allow a deeper and more nuanced understanding of the related financial statement accounts and disclosures. Furthermore, investors have consistently stated that having the auditor rather than the company, provide this type of information would be of added value to investment decision making.⁹⁶ Commenting on the reproposal, the SEC’s Investor Advocate noted that investors want to hear directly from the auditor and that this point is confirmed by surveys of professional investors, as well as by certain academic research.⁹⁷ This commenter agreed with the premise in the reproposal that, because the auditor is required to be independent, information provided by the auditor may be viewed by investors as having greater credibility than information provided by management alone.

Reporting of critical audit matters should provide insights that will add to the mix of information that could be used in investors’ capital allocation decisions, for example, by:

- Highlighting the aspects of the financial statement audit that the auditor found to be especially challenging, subjective, or complex;
- Enabling comparison of these aspects of the audit across companies, for example audits of companies within the same industry; and
- Enabling comparison of these aspects of the audit for the same company over time.

⁹⁵ It is often not possible to observe the difference between financial reporting quality and audit quality. An academic study conceptually models the path through which the financial reporting and audit processes result in audited financial reporting outcomes. The authors postulate that although audit quality and pre-audit financial reporting quality are distinct constructs, the two processes are often inseparable in terms of observable financial reporting outcomes in archival research. See Lisa Milici Gaynor, Andrea Seaton Kelton, Molly Mercer, and Teri Lombardi Yohn, *Understanding the Relation between Financial Reporting Quality and Audit Quality*, 35 *Auditing: A Journal of Practice & Theory* 1, 1–22 (2016).

⁹⁶ See IAG 2011 survey and CFA survey and poll results.

⁹⁷ See letter from Rick A. Fleming, Investor Advocate, SEC (Aug. 15, 2016) at 3, available on the Board’s Web site in Docket 034 (citing Brant E. Christensen, Steven M. Glover, and Christopher J. Wolfe, *Do Critical Audit Matter Paragraphs in the Audit Report Change Nonprofessional Investors’ Decision to Invest?* 33 *Auditing: A Journal of Practice & Theory* 71, 71–93 (2014)).

Many companies commenting on the reproposal argued that the reporting of critical audit matters would not increase the informativeness of the auditor’s report. For example, several of these commenters claimed that the reporting of critical audit matters would simply duplicate management disclosure without adding additional information, or that critical audit matters would not provide value-relevant information. Other commenters asserted that the reporting of critical audit matters would result in the auditor’s report becoming a lengthy list of boilerplate disclosures, which would contribute to disclosure overload or run contrary to the SEC’s disclosure effectiveness initiative. Several commenters said that critical audit matters could confuse investors if the information in the auditor’s report was duplicative of management’s disclosures but was presented in a different manner, or if the critical audit matter presented information without appropriate context.

By contrast, investor commenters overwhelmingly agreed that the communication of critical audit matters would make the auditor’s report more informative. One commenter said that, although critical audit matters in themselves would not provide investors with all the information needed in the face of growing financial complexity, critical audit matters would add to the total mix of information available to investors, and would contribute to their ability to analyze companies, form a multifaceted understanding of them, and make informed investment decisions. Another commenter noted that, in jurisdictions where the expanded auditor’s report is available, it is one of the earliest elements of the company’s annual report that they read because it typically highlights the more judgmental elements of the company’s accounting, which often provides insights that form a basis for discussions with management.

Mandated Rather Than Voluntary Reporting

Auditors have not developed a practice of providing information in the auditor’s report beyond what is required, even though investors have consistently requested that the auditor’s report become more informative. Current standards provide a framework for auditors to provide limited additional information through emphasis paragraphs,⁹⁸ but in general these only point to a disclosure in the company’s financial statements without providing any additional description of

⁹⁸ See existing AS 3101.19.

⁹³ Section 101(a) of Sarbanes-Oxley.

⁹⁴ The FRC observes that, in some instances, investors have begun to use the information provided in the expanded auditor’s reports in the U.K. to engage with audit committees. See FRC, *Extended Auditor’s Reports, A Further Review of Experience* (Jan. 2016) (“FRC 2016 Report”).

the matter and, as noted below, emphasis paragraphs are infrequent in practice. Auditor reporting about matters significant to the audit is not prohibited in an emphasis paragraph, but current standards do not encourage auditors to include such information in their report and do not provide a framework for doing so.

There are many other potential reasons why auditors are not providing information voluntarily in the auditor's report, whether about the financial statements or the audit. For example, the historical model of management disclosing information and the auditor attesting to the information may lead companies to resist voluntary additional reporting by the auditor, either through emphasis paragraphs or with respect to information about the audit, which the auditor would be better positioned to communicate than management. Further, auditors may believe that providing additional information could potentially expose them to liability or that doing so could be interpreted as a disclaimer of opinion or a partial opinion as to the identified matters. Finally, in general, there may be disincentives to voluntary reporting if the disclosing party is not able to fully capture the benefits of the disclosures,⁹⁹ and parties may also exhibit a bias toward the *status quo*.¹⁰⁰ All of these factors disincentivize auditors from voluntarily providing further information about the audit, even if investors and other financial statement users would respond favorably to receiving additional information.

The Board believes that the required reporting of critical audit matters will promote more complete and consistent disclosure of audit-specific information to financial statement users who may be

interested in it.¹⁰¹ Mandatory disclosure can also improve the allocative efficiency of capital markets by decreasing the costs associated with gathering information, or by providing market participants with information that otherwise would have been difficult or impossible for them to gather.¹⁰²

Additional Improvements to the Auditor's Report

The final standard requires auditors to disclose in the auditor's report the number of years they have served consecutively as the auditor for the company. Although some commenters dispute the value of this information, investor commenters have indicated that the length of the relationship between the auditor and the company would be a useful data point. The growing trend toward voluntary disclosure of this information by companies suggests that increasing numbers of companies believe that the market finds the disclosure useful.¹⁰³ Further, there is a line of academic research suggesting that there is an association between auditor tenure and increases or decreases in audit quality.¹⁰⁴

Although investors may be able to determine auditor tenure by, for example, reviewing past auditor's reports, for many companies the information is not readily available even through a manual search process. Furthermore, while some companies voluntarily provide information about auditor tenure in the proxy statement, many do not. Many companies are also not subject to the proxy rules (for example, most investment companies, foreign private issuers, and many companies whose securities are not listed on a national securities exchange). In cases where the information is provided voluntarily, it is not provided in a consistent location. The Board believes that these issues create unnecessary search costs for investors

who wish to evaluate information about auditor tenure. Mandatory disclosure of auditor tenure in the auditor's report will provide a consistent location for this information and will reduce search costs relative to the current baseline for investors who are interested in auditor tenure, especially in the case of companies that do not voluntarily provide such information or for which the information is not available through the EDGAR system. Mandatory disclosure of auditor tenure in the auditor's report may also be more likely to encourage further discussion of auditor tenure by management and the audit committee and potential disclosure in company filings.

The existing auditor's report also does not describe important aspects of the auditor's responsibilities under existing auditing standards, such as the auditor's responsibility to detect material misstatements, whether due to error or fraud; the auditor's responsibility for the notes to the financial statements; and the auditor independence requirement. This may contribute to misperceptions by investors and other financial statement users about the auditor's role and responsibilities, including with respect to these matters. Academic research suggests that there are a number of ways in which investor perceptions of the role and responsibilities of the auditor may diverge from what current professional standards require.¹⁰⁵ In addition, the existing standards do not require a uniform approach to basic content, such as the addressee of the report and the form of the auditor's report, which may increase the time and costs of processing the information in the auditor's report. The final standard contains provisions requiring the basic elements in the auditor's report to be presented more uniformly.

Commenters generally supported the reproposed changes to these basic elements of the auditor's report. Some commenters noted that the enhanced descriptions of the auditor's responsibility to detect material misstatements would clarify the auditor's responsibilities for financial

⁹⁹ Academic research finds that there are certain situations in which disclosure may be socially optimal but not privately optimal. Auditors and companies may resist voluntary expanded auditor reporting because of concerns that certain types of spillover effects (or externalities) may create a competitive disadvantage. For a summary of this line of research, see Luigi Zingales, *The Future of Securities Regulation*, 47 Journal of Accounting Research 391, 394–395 (2009). Professor Zingales is the founding director of the PCAOB's Center for Economic Analysis, now known as the Office of Economic and Risk Analysis. The research cited above was published before he joined the PCAOB.

¹⁰⁰ Research in behavioral economics suggests that when facing a set of decisions, individuals are more likely to stick to the known outcome (*status quo*) than would be expected based on the theory of rational decision making under uncertainty. There are a variety of reasons why individuals may choose the status quo outcome in lieu of an unknown outcome, including aversion to the uncertainty inherent in moving from the status quo to another option. See William Samuelson and Richard Zeckhauser, *Status Quo Bias in Decision Making*, 1 Journal of Risk and Uncertainty 7, 7–59 (1988).

¹⁰¹ Academic research on disclosure explores these types of positive externalities, as well as certain negative externalities. See, e.g., Ronald A. Dye, *Mandatory versus Voluntary Disclosures: The Cases of Financial and Real Externalities*, 65 The Accounting Review 1, 1–24 (1990); or Anat R. Admati and Paul Pfleiderer, *Forcing Firms to Talk: Financial Disclosure Regulation and Externalities*, 13 The Review of Financial Studies 479, 479–519 (2000).

¹⁰² See, e.g., John C. Coffee, Jr., *Market Failure and the Economic Case for a Mandatory Disclosure System*, 70 Virginia Law Review 717, 717–753 (1984).

¹⁰³ See Center for Audit Quality and Audit Analytics, 2016 Audit Committee Transparency Barometer (Nov. 2016). See also Ernst & Young, *Audit Committee Reporting to Shareholders 2016* (Sept. 2016).

¹⁰⁴ See below for a discussion of academic research regarding auditor tenure.

¹⁰⁵ See, e.g., Bryan K. Church, Shawn M. Davis, and Susan A. McCracken, *The Auditor's Reporting Model: A Literature Overview and Research Synthesis*, 22 Accounting Horizons 69, 69–90 (2008); Glen L. Gray, Jerry L. Turner, Paul J. Coram, and Theodore J. Mock, *Perceptions and Misperceptions Regarding the Unqualified Auditor's Report by Financial Statement Preparers, Users, and Auditors*, 25 Accounting Horizons 659, 675–676 (2011); or Theodore J. Mock, Jean Bédard, Paul J. Coram, Shawn M. Davis, Reza Espahbodi, and Rick C. Warne, *The Audit Reporting Model: Current Research Synthesis and Implications*, 32 Auditing: A Journal of Practice & Theory 323, 323–351 (2013).

statement users, other commenters offered suggestions for refinement, such as aligning the requirements to the IAASB model or amending the description to more clearly define the auditor's role within the context of the financial reporting regulatory framework.

Commenters also generally supported including a statement on the auditor's independence requirement. For example, some commenters stated that adding a statement by the auditor on their independence would reinforce investors' understanding of the auditor's requirement to remain independent and objective in expressing the audit opinion. Other commenters said that the enhanced description of the independence requirement could provide a meaningful reminder of the importance of auditor independence. However, other commenters said that the enhanced description of auditor independence was either unnecessary, or would not have a significant impact on auditor behavior. Based on broad commenter support, the Board is adopting these additional improvements to the auditor's report as repropoed.

Baseline

Critical Audit Matters

The auditor's report in the United States today generally consists of three paragraphs that include limited audit-specific information. The existing auditor's report identifies the company's financial statements that were audited, provides a standardized description about the nature of an audit, and provides an opinion on whether the company's financial statements are fairly presented, in all material respects, in conformity with the applicable financial reporting framework. The auditor's report is often described as a pass/fail model because the report only conveys the auditor's opinion on whether the financial statements are fairly presented (pass) or not (fail) and typically provides limited information about the nature of the work on which the opinion is based.

The Board's current standards also require that the auditor add explanatory paragraphs to the auditor's report under specific circumstances, such as when there is substantial doubt about the company's ability to continue as a going concern or a restatement of previously issued financial statements. When included, these paragraphs generally consist of standardized language that provides limited audit-specific information.

The auditor may also, at his or her discretion, include emphasis paragraphs

in the auditor's report to emphasize a matter regarding the financial statements. Generally, an emphasis paragraph only points to a disclosure in the company's financial statements without providing any additional description. Under current practice, emphasis paragraphs are infrequent.¹⁰⁶ Auditors may also, at their discretion, include language in the auditor's report indicating that they were not engaged to examine management's assertion about the effectiveness of internal control over financial reporting.¹⁰⁷

Academic research confirms the view of the Board and many commenters that the current form of the auditor's report conveys little of the audit-specific information obtained and evaluated by the auditor.¹⁰⁸ Academic research also finds that investors and other financial statement users refer to the existing auditor's report only to determine whether the opinion is unqualified because it does not provide much additional informational value about a particular audit.¹⁰⁹ These findings align with the consistent call from investors, over the course of the Board's rulemaking process, for a more informative auditor's report.¹¹⁰

Additional Improvements to the Auditor's Report

The existing auditor's report is not required to have a specified addressee but it may be addressed to the company whose financial statements are being audited, its board of directors, or

stockholders.¹¹¹ Under current practice, the auditor's report is generally addressed to one or more of the following: (1) The board of directors and stockholders/shareholders, or their equivalent for issuers that are not organized as corporations; (2) the plan administrator or plan participants for benefit plans; and (3) the directors or equity owners for brokers or dealers.¹¹²

The current auditor's report also includes the report title, the date, and the name and location of the accounting firm's office issuing the report. The auditor is not currently required to disclose in the auditor's report the number of years it has served as auditor for the company. However, as noted earlier, many larger companies have begun voluntarily disclosing auditor tenure in the proxy statement.

Currently, the title of the auditor's report, "Report of Independent Registered Public Accounting Firm," provides the only indication of the auditor's independence.

Benefits

Critical Audit Matters

Economic theory commonly attributes two benefits to mandatory disclosure. First, the disclosure of previously unknown, value-relevant information directly benefits the market because it allows market participants to make better-informed decisions. Second, the disclosure of such information may indirectly benefit the market because some parties may change their behavior in positive ways after information is disclosed.

Direct Benefit: More Informative and Useful Auditor's Report

The Board believes that auditor communication of critical audit matters will reduce the information asymmetry between investors and auditors, which should in turn reduce the information asymmetry between investors and management about the company's financial performance. Some commenters on the reproposal agreed that the information provided in critical audit matters would be used by various types of investors in a number of different ways that are consistent with the framework outlined in the reproposal:

- *Informing*—Identification of the matters arising from the audit that the auditor considered especially challenging, subjective, or complex,

¹¹¹ See existing AS 3101.09.

¹¹² This information is based on a review by PCAOB staff of a random sample of 2014 fiscal year-end auditor's reports for issuers, benefit plans, and brokers and dealers.

¹⁰⁶ In the audit reports of approximately 6,350 issuers with fiscal year 2014 filings, PCAOB staff identified audit reports containing explanatory paragraphs to emphasize matters in the financial statements in approximately 2 percent of the filings.

¹⁰⁷ See paragraph .10 of AI 20, *Other Information in Documents Containing Audited Financial Statements: Auditing Interpretations of AS 2710*.

¹⁰⁸ See Church et al., *The Auditor's Reporting Model: A Literature Overview and Research Synthesis* 69–90.

¹⁰⁹ See Gray et al., *Perceptions and Misperceptions Regarding the Unqualified Auditor's Report by Financial Statement Preparers, Users, and Auditors* 659–684; Mock et al., *The Audit Reporting Model: Current Research Synthesis and Implications* 323–351.

¹¹⁰ Academic research has found that, in some instances, the inclusion of explanatory language in the auditor's report may provide investors with additional value-relevant information. A recent academic study suggests that auditor's reports containing certain types of explanatory paragraphs required under existing standards may provide information about the likelihood that financial statements will be subsequently restated. The authors argue that the inclusion of such an explanatory paragraph in the auditor's report can provide a signal to investors about the risk of misstatement of the company's financial statements. See Keith Czerney, Jaime J. Schmidt, and Anne M. Thompson, *Does Auditor Explanatory Language in Unqualified Audit Reports Indicate Increased Financial Misstatement Risk?* 89 *The Accounting Review* 2115, 2115–2149 (2014).

together with a description of how the auditor addressed those matters, which should provide valuable information. For example, some commenters said that:

- Critical audit matters would add to the total mix of information available to investors, and would contribute to their ability to analyze companies and make investment decisions;
 - Investors would use critical audit matters in the same way that they use any other financial disclosure; critical audit matters would add an additional perspective to management's disclosures;
 - Insights on critical audit matters may be relevant in analyzing and pricing risks in capital valuation and allocation;
 - Critical audit matters would inform investor models of company financial performance;
 - Critical audit matters would augment and add more dimension to the information provided by the financial statements and the critical accounting policies and estimates; and
 - The communication of critical audit matters would lower the cost of acquiring information for financial statement users.
- *Framing*—Critical audit matters should provide investors with a new perspective on the financial statements and focus their attention on the related financial statement accounts and disclosures, which should facilitate their analysis of the financial statements, and help them assess financial performance, for example by highlighting potentially relevant information or by reducing the costs to process or search for the information. For example, some commenters said that:
- Critical audit matters would focus investors' attention on key financial reporting issues and identify areas that deserve more attention;
 - In jurisdictions where expanded auditor reporting is available, it focuses users' attention on issues that would be pertinent to understanding a company as a long-term investor; and
 - Information in critical audit matters would contribute to investor understanding and consumption of information in the financial statements.
- *Monitoring*—The ability to identify and evaluate the matters identified as critical audit matters should also help investors and analysts engage management with targeted questions about these issues and support investor decisions on ratification of the auditor. For example, some commenters said that:

- Critical audit matters would facilitate the ability of investors to monitor management's and the board of director's stewardship of the company by highlighting accounting and auditing issues and other matters that investors may wish to emphasize in their engagement with management; and
 - Critical audit matters would provide important information on how the auditor has addressed an issue, which investors can use in evaluating the rigor of the audit and making proxy voting decisions, including ratification of the audit committee's choice of external auditor.
- Critical audit matters may be used by different types of investors in different ways. For example, retail investors (or others who may act on their behalf, such as analysts, credit rating agencies, or the financial press) may use the additional information to help them identify and analyze important aspects of the financial statements. Larger investors, on the other hand, may also use critical audit matters as a basis for engagement with management.

The communication of critical audit matters aims to provide investors and financial statement users with specific information about the audit of a company's financial statements. Some commenters were concerned, however, that the communication of critical audit matters could lead to a reduction in comparability of auditor's reports. Although differences in critical audit matters from period to period and across companies may make auditor's reports less uniform, to the extent the information provided is useful in evaluating the financial performance, highlighting these differences should contribute to the overall mix of information. Further, some commenters on the proposal said that investors are interested in information that is specific to the audit of a company's financial statements, and therefore, would expect differences in auditor's reports across companies and reporting periods. Investors also have indicated that they are accustomed to analyzing company-specific information, such as information in financial statements or MD&A that is specific to a company or a reporting period.

A body of academic research regarding the possible effects of expanded auditor reporting is emerging.¹¹³ The Board has been monitoring this research with a view towards assessing its potential relevance

to this rulemaking. The Board is mindful of several issues that limit the extent to which this research can inform its decision making. Much of this research is unpublished and at a relatively early stage. The current conclusions may be subject to multiple interpretations and it is possible that results from this research may be revised during the peer review process. Moreover, it may be difficult to generalize results outside the context of specific studies. For example, in considering the implications of academic studies based on data from other jurisdictions, differences between the Board's final standard and the requirements in other jurisdictions must be taken into account. In addition, specific characteristics of the U.S.-issuer audit market may make it difficult to generalize observations made in other markets because of differences in baseline conditions (for example, market efficiency, affected parties, policy choices, legal environment, and regulatory oversight). As to experimental research in particular, it should be noted that the experimental setting may not provide study participants with information that is representative of the information environment in which market participants actually operate; for instance, if new information appeared more salient to study participants than it would to a market participant, the impact of expanded auditor reporting would be overstated in an experimental setting. In addition, some of these studies were conducted based on earlier versions of rule text that differs from the final standard, which may affect the extent to which the results can inform the Board in evaluating potential effects of the final standard.

As discussed in more detail in the economic analysis contained in the reproposal, the results from early research analyzing the informational value of expanded auditor reporting are inconclusive.¹¹⁴ Some studies found that expanded auditor reporting could provide investors with new and useful information, while other studies found that the benefits attributable to expanded auditor reporting were not statistically significant, but that it could produce unintended consequences. These limited findings may be due to the fact that the results of the studies represent averages for large samples of companies. On average, investors may already have access to a variety of information sources (such as annual reports, news media, and analyst

¹¹³ For a review of relevant academic research, see Jean Bédard, Paul Coram, Reza Espahbodi, and Theodore J. Mock, *Does Recent Academic Research Support Changes to Audit Reporting Standards?* 30 *Accounting Horizons* 255, 255–275 (2016).

¹¹⁴ See PCAOB Release No. 2016–003, Section VI.C.1.a.

research reports) which may contain similar information about a company. However, expanded auditor reporting may be relatively more informative for companies where alternative sources of information are less available (e.g., those companies with less analyst coverage).

In response to the reproposal, two commenters submitted studies suggesting that expanded auditor reporting has increased the informative value of the auditor's report. One experimental study tested the communicative value of expanded auditor reporting by analyzing how key audit matters affected investment professionals' assessment of a company's business economics, as well as their confidence in making that assessment.¹¹⁵ The authors found that specific informational content of the key audit matter affected the study participants' perceived level of trust associated with the auditor's report, which then affected the perceived level of trust associated with the financial statements and their assessment of the company's business economics. Another study analyzed whether the communicative value of auditor's reports changed following the implementation of expanded auditor reporting in the United Kingdom.¹¹⁶ The author found that the readability of auditor's reports increased in the post-implementation period, and that the use of negative and uncertain words in expanded auditor's reports captured more client-specific audit risk.¹¹⁷ In addition, the author found limited evidence that the dispersion of analysts' EPS forecasts decreased following the implementation of expanded auditor reporting, suggesting an improved information environment. The author argued that expanded auditor reporting was successful at increasing the communicative value of the auditor's report, and that analyst behavior changed accordingly. In contrast, another recent experimental study found that including critical audit matters reduced the readability of the auditor's report but did not

incrementally inform nonprofessional investors' valuation judgments. However, the study suggested that the reporting of a critical audit matter lowers nonprofessional investors' perceptions of management's credibility when earnings just meet analysts' expectations. The study was designed and implemented using the definition of critical audit matters and related reporting requirements from the Board's proposal, which differ from the final standard.¹¹⁸

In addition, in reviewing the experience of expanded auditor reporting in the United Kingdom, the FRC observed that investors greatly value the information provided in expanded auditor reporting.¹¹⁹ This view is confirmed by UK investors that commented on the reproposal. The FRC noted that, in the two years following the implementation of the new requirements, an association of investment managers has recognized in an annual awards ceremony those specific auditor's reports found to be most clear and most innovative in providing insight into the audit of the company's financial statements.¹²⁰ In addition, the FRC notes that users of the new auditor's reports identified certain descriptions of risks that they found to be more useful—such as descriptions that are specific to the entity being audited. Further, the FRC report noted that, in the second year of implementation, a much greater proportion of risks were set out in a more meaningful and transparent way.¹²¹ As noted above, the FRC's requirements for expanded auditor reporting are different from the final standard, and the baseline legal and regulatory environment is not the same as in the United States. Nevertheless, the Board believes that there are sufficient similarities for the UK experience to be generally informative in its decision-making.

While it is too early for the body of academic research on expanded auditor reporting to provide a conclusive answer, investors commenting during the Board's standard-setting process have consistently affirmed the usefulness of expanded auditor reporting and the FRC's observations on the early experience of investors in the

United Kingdom are consistent with this view. Accordingly, the Board believes that auditor communication of critical audit matters will add to the mix of information that investors can use.

Indirect Benefit: Improved Audit and Financial Reporting Quality

In general, information asymmetry can lead to situations in which an agent (such as an auditor) takes actions that do not coincide with the best interests of the principal (such as an investor), if the agent's incentives are misaligned.¹²² This type of problem is the result of the inability of the principal to observe or monitor the agent's behavior, which also inhibits the principal's ability to identify and reward optimal behavior, or punish sub-optimal behavior. Economic theory posits that the disclosure of information can have indirect effects that lead to changes in behavior.¹²³ In the context of expanded auditor reporting, the additional information provided in the auditor's report could be beneficial to investors by providing more information about the audit, which could affect their voting decisions. To the extent that this could influence the terms of the auditor's engagement, academic research suggests "any additional information about the agent's action, however imperfect, can be used to improve the welfare of both the principal and the agent."¹²⁴

This suggests that making aspects of the audit more visible to investors through the communication of critical audit matters should provide some auditors, management, and audit committees with additional incentives to change their behavior in ways that may enhance audit quality and ultimately financial reporting quality. For instance, the communication of critical audit matters could lead:

- Auditors to focus more closely on the matters identified as critical audit matters;
- Audit committees to focus more closely on the matters identified as critical audit matters and to engage the

¹¹⁵ See Annette Koehler, Nicole Ratzinger-Sakel, and Jochen Theis, *Does the Reporting of Key Audit Matters Affect the Auditor's Report's Communicative Value? Experimental Evidence from Investment Professionals* (working paper submitted as comment letter No. 18, available on the Board's Web site in Docket 034).

¹¹⁶ See Kecia Williams Smith, *Tell Me More: A Content Analysis of Expanded Auditor Reporting in the United Kingdom* (working paper submitted as comment letter No. 71, available on the Board's Web site in Docket 034).

¹¹⁷ The author uses several measures designed to assess the readability of texts which, the study notes, have been used in several other published academic studies addressing the readability of financial disclosure. See *id.* at 5.

¹¹⁸ See Brian Carver and Brad Trinkle, *Nonprofessional Investors' Reactions to the PCAOB's Proposed Changes to the Standard Audit Report* (March 2017) (working paper, available in Social Science Research Network).

¹¹⁹ See FRC 2016 Report.

¹²⁰ See FRC, *March 2015—Extended Auditor's Reports, A Review of Experience in the First Year*; and FRC 2016 Report.

¹²¹ *Id.*

¹²² Economists use principal-agent theory to analyze situations where one party (the principal) hires another party (the agent) to perform certain tasks and decision-making ability is delegated to the agent. For a general discussion of principal-agent theory, see, e.g., Michael C. Jensen and William H. Meckling, *Theory of the Firm: Managerial Behavior, Agency Costs and Ownership Structure*, 3 *Journal of Financial Economics* 305, 305–360 (1976), or Bengt Holmstrom, *Moral Hazard and Observability*, 10 *The Bell Journal of Economics* 74, 74–91 (1979).

¹²³ See, e.g., George Loewenstein, Cass R. Sunstein, and Russell Golman, *Disclosure: Psychology Changes Everything*, 6 *Annual Review of Economics* 391, 391–419 (2014).

¹²⁴ See Holmstrom, *Moral Hazard and Observability* at 75.

auditor and management about the adequacy of the related disclosures; and

- Management to improve the quality of their disclosures because they know that investors and the auditor will be scrutinizing more closely the matters identified as critical audit matters.

The communication of critical audit matters could lead auditors to increase their focus on the matters identified in the auditor's report as critical audit matters. As suggested by commenters, the communication of critical audit matters could further incentivize auditors to demonstrate the level of professional skepticism necessary for high quality audits in the areas of the critical audit matters. Other commenters stated that the reporting of critical audit matters could result in increased audit quality. For example, auditors could feel that the potentially heightened scrutiny of the matters identified as critical audit matters may warrant additional effort to satisfy themselves that they have obtained an appropriate amount of audit evidence to support their opinion.

The communication of critical audit matters could also heighten management's attention to the relevant areas of financial statements and related disclosures. Several commenters stated that the reporting of critical audit matters would lead management to improve the quality of their disclosures or adopt more widely accepted financial reporting approaches in these areas.¹²⁵

An experimental study analyzed the joint effect of expanded auditor reporting and audit committee oversight on management disclosure choices.¹²⁶ The author found that the study participants, who were currently serving as public company financial executives, chose to provide the greatest level of disclosure when they knew that the auditor's report would provide a more detailed description of the accounting estimate, and the audit committee exhibited strong oversight. The author argued that, similar to what other academic research has found regarding the resolution of audit adjustments, information presented in critical audit

matters would be the outcome of a negotiation process between the auditor and management.

Increased management attention to the related aspects of the financial statement accounts and disclosures described in the critical audit matters should, at least in some cases, lead to an incremental increase in the quality of the information presented. Academic research has shown that increased quality of information could result in a reduction in the average cost of capital.¹²⁷

In addition, the communication of critical audit matters may enhance the audit committee's oversight efforts by providing an additional incentive for the audit committee to engage with the auditor and management about the matters identified as critical audit matters and the adequacy of the company's related disclosures. Although some commenters stated that the required communication of critical audit matters would "chill" communications between the auditor and the audit committee, others said that it would enhance communications between these parties. Further, it should be noted that the final standard does not change the Board's existing requirements on audit committee communications, other than requiring the auditor to provide the audit committee with a draft of the auditor's report.

To the extent changes in the behavior of auditors, audit committees, and management occur, they could lead to an incremental increase in audit quality and financial reporting quality, which should increase investors' confidence in the reliability of the financial statements. Some commenters stated that a more transparent and informative auditor's report could heighten user confidence in the audit and the audited financial statements. Academic research suggests that an increase in investor confidence should decrease the average cost of capital.¹²⁸ As discussed in the economic analysis of the reproposal, some empirical studies conducted in other jurisdictions provide evidence

that expanded auditor reporting increased audit quality, while other studies found that it did not have a measurable effect on audit quality.¹²⁹ The Board is not aware of any empirical studies indicating that expanded auditor reporting had a negative effect on audit quality.

Indirect Benefit: Differentiation Among Auditor's Reports

If investors and other financial statement users perceive and respond to differences in the quality and usefulness of the information communicated by auditors regarding critical audit matters, expanded auditor reporting should serve as a potential means of greater differentiation among accounting firms and engagement partners.¹³⁰ One commenter stated that the reporting of critical audit matters would allow auditors to differentiate themselves, and that this differentiation would provide useful information to investors and other financial statement users. If expanded auditor reporting allows investors to differentiate among accounting firms and engagement partners, it should provide a more nuanced signal of audit quality and financial reporting reliability.

The FRC report also noted that there are clear differences among accounting firms in the approaches taken to implement the requirements.¹³¹ For example, one firm went beyond the FRC's requirements by including audit findings for the risks of material misstatement in the majority of its auditor's reports in the second year of implementation, which other firms did far less frequently. The FRC's observations may suggest that accounting firms took different approaches to expanded auditor reporting as a means of distinguishing themselves based on the quality and usefulness of the information provided in their auditor's reports. Furthermore, as discussed in the economic analysis of the reproposal, an academic study argued that investors found the auditor's reports issued by some accounting firms to be more useful than others.¹³² One commenter specifically noted that mandatory auditor rotation was introduced in the UK at the same time

¹²⁵ To substantiate this point, one commenter cited a memo prepared for the clients of an international law firm that noted management should consider revising or supplementing their own disclosures relating to issues raised in expanded auditor's reports to ensure that the totality of disclosures around the issue are complete and accurate. See Sullivan & Cromwell LLP, *Audit Reports, PCAOB Releases Reproposal of Amendments to Its Audit Report Standard* (May 25, 2016).

¹²⁶ See Stephen H. Fuller, *The Effect of Auditor Reporting Choice and Audit Committee Oversight Strength on Management Financial Disclosure Decisions* (working paper submitted as comment letter No. 49, available on the Board's Web site in Docket 034).

¹²⁷ See, e.g., Richard A. Lambert, Christian Leuz, and Robert E. Verrecchia, *Information Asymmetry, Information Precision, and the Cost of Capital*, 16 *Review of Finance* 1, 1–29 (2012). Professor Leuz is an economic advisor at the PCAOB. The research cited above was published before he joined the PCAOB.

¹²⁸ See Luigi Guiso, Paola Sapienza, and Luigi Zingales, *Trusting the Stock Market*, 63 *The Journal of Finance* 2557, 2557–2600 (2008). Professor Zingales is the Founding Director of the PCAOB's Center for Economic Analysis, now known as the Office of Economic and Risk Analysis. The research cited here was published before he joined the PCAOB.

¹²⁹ See PCAOB Release No. 2016–003, Section VI.C.1.b, footnotes 154–156 and accompanying text.

¹³⁰ On May 9, 2016, the SEC approved new rules and related amendments to the Board's auditing standards, including amendments to AS 3101, that will provide investors and other financial statement users with information about engagement partners and other accounting firms that participate in audits of issuers. See PCAOB Release No. 2015–008.

¹³¹ See FRC 2016 report.

¹³² See PCAOB Release No. 2016–003, Section VI.C.1.b, footnote 161 and accompanying text.

as expanded auditor reporting, and that this may have provided accounting firms with motivation to differentiate themselves.

In addition to relying on the audit committee (which, at least for exchange-listed companies, is charged with overseeing the external auditor), in the absence of differentiation based on the auditor's report, users of financial statements may rely on proxies such as the reputation of the accounting firm issuing the auditor's report, aggregated measures of auditor expertise (for example, dollar value of issuer market capitalization audited or audit fees charged), or information about the geographic location of the office where the auditor's report was signed as signals for audit quality. Academic research finds, however, that these are imperfect signals of audit quality.¹³³

The identification and description of critical audit matters should permit differentiation among auditor's reports based on investor perceptions of their informativeness and usefulness. In some instances it may also provide a signal of audit quality. Because the determination and communication of critical audit matters may reflect a variety of considerations, however, critical audit matters may not bear directly on audit quality. For example, the choice of which critical audit matters to communicate or how to describe them may reflect considerations such as the company's business environment and financial reporting choices, accounting firm methodology, engagement partner characteristics, and legal advice. Thus, a more detailed description of critical audit matters may not necessarily reflect a higher quality audit than a less informative description of such matters.

Nevertheless, informative descriptions of how the audit addressed critical audit matters should provide insight into the extent and appropriateness of the auditor's work. Moreover, it is possible that thoughtful, audit-specific, and useful critical audit matters (or, conversely, generic and uninformative critical audit matters) could affect investor perceptions of the auditor's work and willingness to provide useful information. As a result, the communication of critical audit matters, potentially in conjunction with disclosures regarding the identity of the engagement partner and other accounting firms that participated in the

audit,¹³⁴ and other relevant information should enable differentiation among engagement partners and accounting firms on that basis.

Additional Improvements to the Auditor's Report

The final standard will introduce new requirements regarding auditor tenure, the addressee of the auditor's report, and statements in the auditor's report related to auditor independence and the auditor's responsibility for reporting on ICFR.¹³⁵ In addition, the final standard contains other changes to the form of the auditor's report, which are intended to improve and clarify the language for certain elements, such as statements related to the auditor's responsibilities regarding the notes to the financial statements, and to promote a consistent presentation of this information across auditor's reports.

Investor commenters have consistently supported disclosing tenure in the auditor's report. In the Board's view, which is consistent with the views of some commenters,¹³⁶ disclosing information about auditor tenure in the auditor's report will provide a consistent location for this information and decrease the search costs, relative to the current environment of voluntary reporting, for some investors and other financial statement users who are interested in this information.

The statement regarding the auditor's existing obligation to be independent of the company is intended to enhance investors' and other financial statement users' understanding about the auditor's obligations related to independence and to serve as a reminder to auditors of these obligations. By requiring the auditor's report to be addressed to certain parties, the Board will be promoting uniformity in the addressees of the auditor's report.

Commenters were generally supportive of the proposed changes to the form of the auditor's report. For example, some commenters stated these enhancements would make the auditor's report easier to read and would facilitate comparisons between auditor's reports for different companies by providing a consistent format.

¹³⁴ See PCAOB Release No. 2015-008.

¹³⁵ In circumstances where management is required to report on ICFR but the auditor is not and has not performed an audit of ICFR, the final standard requires a statement to that effect in the auditor's report.

¹³⁶ See below for a discussion of academic research regarding auditor tenure.

Costs and Potential Unintended Consequences

Costs

Commenters on the reproposal raised concerns that the rule would impose various types of costs, but generally did not quantify those costs. Even those that, at an earlier stage of the rulemaking, conducted limited implementation testing of the proposal were unable to provide a quantified cost estimate. Given lack of data, the Board is unable to quantify costs, but provides a qualitative cost analysis.

As an additional means of assessing potential cost implications of the final standard, PCAOB staff has reviewed data from the first year of implementation of expanded auditor reporting in the United Kingdom.¹³⁷ As discussed below, staff analyzed a variety of data points that may be associated with potential costs, including audit fees, days required to issue the auditor's report, and the content of the expanded auditor's report. It should be noted that it may be difficult to generalize observations from the UK experience. For example, the reporting and documentation requirements relating to expanded auditor's reports in the United Kingdom differ from those in the final standard, the baseline legal environments are different, and the UK requirements apply only to companies with a premium listing on the London Stock Exchange and not, for example, to smaller companies that list on London's AIM market.

Critical Audit Matters

The Board anticipates that the final requirements regarding critical audit matters will have potential cost implications for auditors and companies, including their audit committees. Such costs will likely relate to additional time to prepare and review auditor's reports, including discussions with management and audit committees, as well as legal costs for review of the information provided in the critical audit matters. In addition, auditors may choose to perform more audit procedures related to areas reported as critical audit matters (even though performance requirements have not changed in those areas), with cost implications for both auditors and companies.

For auditors, costs might represent both one-time costs and recurring costs. One-time costs could be incurred as a

¹³³ See, e.g., Jere R. Francis, *A Framework for Understanding and Researching Audit Quality*, 30 *Auditing: A Journal of Practice & Theory* 125, 125-152 (2011) and Mark DeFond and Jieying Zhang, *A Review of Archival Auditing Research*, 58 *Journal of Accounting and Economics* 275, 275-326 (2014).

¹³⁷ See PCAOB, *White Paper on the Auditor's Reports of Certain UK Companies that Comply with International Auditing Standard (UK and Ireland)* 700 ("PCAOB White Paper") (May 2016), available on the Board's Web site in Docket 034.

result of: (1) Updating accounting firm audit and quality control methodologies to reflect the new reporting requirements; and (2) developing and conducting training of accounting firm personnel on the new reporting requirements. When updating methodologies, some accounting firms will likely also develop new quality control processes related to additional review or consultation on the determination, communication, and documentation of critical audit matters. One commenter suggested that the initial implementation costs could place a significant and possibly disproportionate burden on smaller accounting firms.

Recurring costs will primarily reflect additional effort expended in individual audits. The final standard does not impose new performance requirements other than the determination, communication, and documentation of critical audit matters, which will be based on work the auditor has already performed. However, there will be some additional recurring costs associated with drafting descriptions of critical audit matters and related documentation. It is likely that senior members of the engagement teams, such as partners and senior managers, will be involved in determining the critical audit matters and developing the language to be included in the auditor's report. In addition, reviews by others, such as the engagement quality reviewer and national office, will also result in recurring costs. Additional time might also be incurred by the auditor as a result of discussions with management or the audit committee regarding critical audit matters.

Companies, including audit committees, will likely also incur both one-time and recurring costs as a result of the final standard. One-time costs could be incurred, for example, in educating audit committee members about the requirements of the new standard and in developing management and audit committee processes for the review of draft descriptions of critical audit matters and the related interaction with auditors. Recurring costs will include the costs associated with carrying out those processes, as well as any increase in audit fees associated with the new reporting requirements or legal fees stemming from a review of critical audit matter communications.

If the drafting and review of critical audit matter reporting takes place towards the end of the audit, there will also be an opportunity cost associated with the time constraints on the parties involved (including, for example,

management, the engagement partner, the audit committee, and the auditor's and company's respective legal counsel). The end of the audit is a busy period in which multiple issues may need to be resolved before the auditor's report can be issued. At the same time, companies and management may also be in the process of finalizing the annual report. Time spent drafting and reviewing the communication of critical audit matters could occur at the same time as other important work in the financial reporting and audit process, and would likely involve senior management that command relatively high annual salaries or experienced auditors and lawyers with relatively high hourly billing rates. In addition, the communication of critical audit matters could lead to changes in management's disclosures, which may result in more effort and cost in the financial reporting process.

Several commenters on the reproposal claimed that the required reporting of critical audit matters would lead to increased audit fees, but none provided data or estimates regarding the magnitude of the increases they expected. Commenters on the proposal had differing views about the likely magnitude of direct costs associated with auditor reporting of critical audit matters. Some commenters said that there would not be material additional costs for communication of critical audit matters, as these matters would already have been communicated to the audit committee. This may suggest that a substantial amount of the work required to communicate critical audit matters would already have been completed earlier in the audit.

One commenter argued that the changes described in the reproposal would lead to a significant increase in costs, and that no compelling case had been made that the benefits would exceed the costs. Some commenters noted that investors would be expected to ultimately bear the cost of the audit, and these commenters have voiced strong support for expanded auditor reporting since the project's inception. This suggests that they consider the benefits of expanded auditor reporting to justify the costs, and would support additional fees for additional useful information.

Audit fees do not fully reflect the cost of implementing expanded auditor reporting to the extent that accounting firms choose to absorb those additional costs and because audit fees do not reflect the impact of any additional demand on management's time associated with expanded auditor reporting. Subject to those limitations,

in its review of the implementation of expanded auditor reporting in the United Kingdom, the PCAOB staff did not find evidence of statistically significant increases in audit fees following the first year of expanded auditor reporting.¹³⁸ For 53 percent of the companies analyzed, audit fees for the year of implementation remained the same or decreased as compared to the prior year's audit fees. Audit fees increased for the remaining companies. The PCAOB staff found that the average change in audit fees was an increase of approximately 5 percent, roughly consistent with the findings of academic research described in the economic analysis in the reproposal. However, the staff found that the median change in audit fees was zero. Collectively, these results seem to suggest that outlier companies with relatively large increases in audit fees drove the result for the average change in audit fees. It should be noted that the PCAOB staff's review did not analyze whether other factors, such as inflation, changes in the economic environment and corporate risk, corporate acquisitions, or the implementation of other regulatory changes, contributed to the documented increase in audit fees.

One commenter on the reproposal noted that the caveats described above are important because the inability to fully gauge the costs of expanded auditor reporting could lead the Board to underestimate the costs associated with the rule, which may bear disproportionately on smaller companies and their auditors. Another commenter also asserted that the costs of expanded auditor reporting are likely to be disproportionately borne by smaller companies because the repropose rule had, in their estimation, limited scalability. The Board believes that the complexity and costs associated with determining, documenting, and communicating critical audit matters should generally depend on the nature and complexity of the audit. This would in turn depend on the complexity of the operations and accounting and control systems of the company.

Additional Improvements to the Auditor's Report

The changes adopted to the basic elements of the auditor's report do not represent a significant departure from the reproposal. Some of the enhanced basic elements will have cost implications for auditors, although these costs are not expected to be significant. One-time costs will primarily relate to updating methodology and training and

¹³⁸ *Id.*

the initial determination of the first year the auditor began serving consecutively as the company's auditor. Based on comments received, it does not appear that the changes adopted to the basic elements will impose significant recurring costs, because the year in which tenure began will not change and the other amendments involve standardized language that, once implemented, will be the same or very similar across different auditor's reports every year.

Potential Unintended Consequences Time Needed To Issue the Auditor's Report

As a result of the additional effort required to determine, communicate, and document critical audit matters, some commenters said that it would take auditors longer to issue their reports. On this point, the PCAOB staff study did not find evidence that compliance with the United Kingdom's expanded auditor reporting requirements delayed the issuance of auditor's reports in the first year of implementation. Based on the study, for companies that had three years of financial statements, a new form auditor's report was issued, on average, in 63 days from the company's fiscal year end date in the year of implementation, as compared to 64 days in the prior year and 65 days two years earlier. Further, academic research cited in the economic analysis of the reproposal similarly did not find that the UK reporting requirements led to delays in financial reporting.¹³⁹

Number and Content of Critical Audit Matters

Some commenters indicated an expectation that the auditor's report would include a long list of critical audit matters or that auditors would have incentives to communicate an overly long list of critical audit matters. For example, some commenters said that this would occur because the auditor would be motivated to communicate as much as possible in an effort to mitigate any future liability for unidentified critical audit matters, or as a means to avoid potential consequences of being second-guessed by regulators or others. Other commenters asserted that such a development could make the auditor's report overly long, contributing to disclosure overload and conflicting with the SEC's disclosure effectiveness project. Other commenters indicated that expanded auditor reporting could

lead to boilerplate language that would diminish the expected value of the critical audit matters and obscure the clarity of the auditor's opinion. If auditors fail to provide audit-specific information, the communication of critical audit matters will not decrease information asymmetry about the audit, and may obscure other important information included in the auditor's report and the audited financial statements.

The final requirements aim to provide investors with the auditor's unique perspective on the areas of the audit that involved the auditor's especially challenging, subjective, or complex judgments. Limiting critical audit matters to these areas should mitigate the extent to which expanded auditor reporting could become standardized. Focusing on auditor judgment should limit the extent to which expanded auditor reporting could become duplicative of management's reporting. Also, while some commenters argued that liability concerns would increase the number of critical audit matters auditors communicate, others suggested that liability concerns would minimize the additional statements auditors make.

The PCAOB staff study did not find evidence that expanded auditor reporting in the United Kingdom resulted in a very large number of risk topics or none at all in the first year of implementation.¹⁴⁰ On average, the auditor's reports in the first year of implementation included descriptions of four risk topics, with total risk topics ranging from one to eight. Additionally, the descriptions of the risks of material misstatement in the auditor's reports in the first year of implementation were not presented in standardized language, but included variations in content length, description, and presentation. The most frequently described risk topics related to revenue recognition, tax, and goodwill and intangible assets. The FRC report on the first two years of expanded auditor reporting in the United Kingdom finds a similar range and average number of risk topics disclosed in both the first and second year of implementation.¹⁴¹ The FRC report also finds disclosure of similar risk topics in the second year of implementation of expanded auditor reporting in the United Kingdom.¹⁴²

Further, the FRC found that, in the second year of expanded auditor reporting in the United Kingdom, the discussion of risks has improved relative to the first year of

implementation and that the majority of auditor's reports provided discussion of risks that were more tailored to the company under audit, thus avoiding generic or standardized wording.¹⁴³ These findings suggest that, thus far, expanded auditor reporting has not become standardized in the United Kingdom.¹⁴⁴

Effects of Increased Attention to Critical Audit Matters

The communication of critical audit matters could lead auditors, company management, and the audit committee to spend additional time and resources on reviewing the adequacy of the work performed on the related financial statement accounts and disclosures. While this could lead to an incremental improvement in audit and financial reporting quality for the identified critical audit matters, it is also possible that there may be increased costs for auditors as a result of the requirements. For example, even though the final standard does not mandate the performance of additional audit procedures other than with respect to communication of critical audit matters, it is possible that some auditors may perform additional procedures. If that occurs, the associated costs may be passed on—in whole, in part, or not at all—to companies and their investors in the form of higher audit fees. Further, increased procedures may also require additional time from the company's management to deal with such procedures. Some commenters suggested that the increased attention on certain matters could also lead to a related decrease in audit and financial reporting quality if other material aspects of the financial statements and disclosures receive less attention.

Some commenters argued that including critical audit matters in the auditor's report would impair the relationship between auditors and management or auditors and the audit committee. Other commenters suggested that the required reporting of critical audit matters would inhibit communication among the auditor, management, and the audit committee because of concerns about what would be publicly communicated in the auditor's report. One commenter also suggested that auditors may include additional matters in audit committee communications out of concern that an

¹⁴³ *Id.*

¹⁴⁴ The Board finds the UK experience instructive, although it is, of course, possible that differences between the UK and U.S. litigation and regulatory environments may influence the extent to which these findings would generalize to the U.S. market.

¹³⁹ See PCAOB Release No. 2016-003, section VI.D.2.a, footnote 169 and accompanying text.

¹⁴⁰ See PCAOB White Paper.

¹⁴¹ See FRC 2016 Report.

¹⁴² *Id.*

omission could lead to regulatory sanctions or liability. Other commenters have said that it would enhance communication among the participants in the financial reporting process.

An experimental study analyzed how the strength of audit committee oversight of the financial reporting process varied with the presence of sophisticated investors and knowledge of forthcoming expanded auditor reporting.¹⁴⁵ The author found that study participants, most of whom were experienced audit committee members, asked fewer probing questions if they knew that the auditor would be providing a discussion of the significant accounting estimate in the auditor's report. The author argued that by asking fewer probing questions audit committee members subconsciously insulated themselves from potential challenges mounted by investors regarding the appropriateness of the company's financial reporting. The Board is not aware of evidence this has occurred in the jurisdictions that have adopted expanded auditor reporting. Moreover, it may be difficult in an experimental setting to recreate the actual legal responsibility and potential liability that audit committee members face, which may limit the extent to which the experimental results would generalize to actual behavior in real-world settings.

Similarly, as described in the economic analysis of the reproposal and asserted by at least one commenter, management may have an incentive to withhold information from the auditor in order to prevent an issue from being described in the auditor's report. It seems unlikely, however, that management would or could withhold information from the auditor on the most critical issues in the audit because it could result in a scope limitation. On the contrary, it may be just as likely that management would communicate more information to the auditor as a means of demonstrating that an issue is not challenging, subjective, or complex, and, therefore, would not need to be described in the auditor's report.

Under the final standard, critical audit matters are determined from the matters communicated or required to be communicated to the audit committee. As noted earlier, with respect to any matters already required to be communicated to the audit committee, there should not be a chilling effect or

reduced communications to the audit committee. Therefore, it would seem that any chilling effect would relate to matters that are not explicitly required to be communicated to the audit committee, although, as previously described, given the breadth of current communication requirements, the Board believes there will likely be few communications affected by that possibility.

Potential Impact on Management Disclosure

Several commenters stated that the communication of critical audit matters would give auditors leverage to encourage disclosure of information by management. While some commenters asserted that this would be beneficial, others claimed it would be an unintended negative consequence of requiring the communication of critical audit matters. Several commenters characterized this as inappropriately expanding the role of the auditor in the financial reporting process, while undermining the role of management and the audit committee. In their view, this would be especially problematic if the final standard permitted the auditor to communicate information that was not otherwise required to be disclosed (for example, because it did not meet a specified threshold for disclosure, such as a significant deficiency in internal control over financial reporting). Commenters claimed that auditor communication of this "original information" would cause a number of unintended consequences, including significant costs, disclosure of confidential or competitively sensitive information, and potentially misleading or incomplete information.

Investors and other commenters pointed out that, although expanded auditor reporting would give the auditor additional leverage over management's disclosure choices, this could result in improvements in the usability of financial statements and increases in financial reporting quality. One of these commenters cited academic research noting that, in current practice, disclosure is already guided by an iterative process between management and the auditor. This commenter reasoned that concerns regarding "original information" were misplaced because the iterative process would reduce the likelihood that the auditor would be a source of original information since critical audit matters would likely overlap with increased management disclosure.

Another commenter pointed out that auditors would not have incentives to interpret the Board's rule to require

disclosure of original information in most situations. For example, concerns about the limitations of their knowledge and expertise, potential liability implications, and friction in the relationship with the company are likely to discourage auditors from going beyond management disclosures. Nevertheless, the final standard contemplates that the auditor will do so only when it is necessary to describe the principal considerations that led the auditor to determine that a matter was especially challenging, subjective, or complex and how the matter was addressed in the audit. The Board believes that this provision is needed in order to ensure that the fact that management did not provide a disclosure would not prevent the auditor from communicating a critical audit matter.

Although the communication of critical audit matters may lead to changes in the incentives for the auditor, company management, and the audit committee to communicate with each other, initial anecdotal evidence from the Board's outreach activities suggests that the implementation of expanded auditor reporting in the United Kingdom has not chilled such communications.

Changes in Perceived Assurance on the Auditor's Report, Including Perceptions of Auditor Liability

The communication of critical audit matters could have liability implications for auditors. In addition, because the communication of critical audit matters requires auditors to discuss aspects of the audit that they found to be especially challenging, subjective, or complex, it is possible that some investors and financial statement users may misconstrue the communications to mean that auditors were unable to obtain reasonable assurance about the matters identified as critical audit matters. Some commenters have said that the communication of critical audit matters could lead to changes in the way investors and financial statements users perceive the level of assurance provided by the auditor on matters identified as critical audit matters, including that it could undermine the basic pass/fail opinion. This could lead investors to erroneously conclude that there is a problem with the audit either in the areas identified in critical audit matters or other areas, or that auditors are providing separate assurance about the presentation of the financial statements, which may have implications for perceptions of auditor responsibility in the event of an audit failure.

¹⁴⁵ Yoon Ju Kang, *Are Audit Committees More Challenging Given a Sophisticated Investor Base? Does the Answer Change Given Anticipation of Additional Mandatory Audit Report Disclosure?* (working paper submitted as comment letter No. 17, available on the Board's Web site in Docket 034).

As discussed in the economic analysis of the reproposal, several academic papers analyze certain risks associated with communicating critical audit matters, including perception of auditor responsibility.¹⁴⁶ If the communication of critical audit matters were to lead to a reduction in perceived auditor responsibility, as is suggested by some academic research, and this in turn reduced auditor liability, it is possible that auditors may feel that less audit work is needed on the matters identified as critical audit matters, which could adversely affect audit quality (although the Board's other auditing standards, reinforced through firm quality control and Board inspections and enforcement activity, should provide a disincentive for auditors to decrease the amount or quality of audit work performed). It is difficult to draw generalizable conclusions based on the findings of these studies. In part, this is because their results vary and are sometimes contradictory, with some studies finding that expanded auditor reporting increases perceived auditor responsibility and others finding that it decreases perceived auditor responsibility. This may suggest that the results are sensitive to the experimental design and the context in which information is presented to study participants. In addition, it is not clear how the findings would correlate with changes in auditor behavior, because perceptions of auditor responsibility may be a poor proxy for actual auditor responsibility or liability.

To address the risk that the communication of critical audit matters could result in the perception of separate assurance, the final standard requires the following statement in the auditor's report:

The communication of critical audit matters does not alter in any way [the auditor's] opinion on the financial statements, taken as a whole, and [the auditor is not] by communicating the critical audit matters . . . providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

The purpose of this statement is to make clear that the communication of critical audit matters in an auditor's report should not be interpreted as altering the level of assurance on any aspect of the audit report, including the identified critical audit matters. In this regard, the Board also notes the view of some commenters that critical audit matters are likely to be used by institutional investors that are unlikely to misinterpret the information.

¹⁴⁶ See PCAOB Release No. 2016-003, Section V.I.D.2.d, footnotes 182-186 and accompanying text.

Auditor Tenure

Many commenters stated that information regarding the auditor's tenure included in the auditor's report could result in inappropriate and inconsistent assumptions about correlations between auditor tenure and/or independence and audit quality. Academic research on the relationship of tenure to audit quality has varied conclusions. For instance, some academic research indicates that engagements with short-term tenure are relatively riskier or that audit quality is improved when auditors have time to gain expertise in the company under audit and in the related industry.¹⁴⁷ Other academic research suggests that, at least prior to 2001, both short tenure (less than five years) and long tenure (greater than fifteen years) can have detrimental effects on audit quality.¹⁴⁸ Still other academic research indicates that investors are more likely to vote against, or abstain from, auditor ratification as auditor tenure increases, which may suggest that investors view long-term auditor-company relationships as adversely affecting audit quality.¹⁴⁹

The disclosure of auditor tenure is intended to add to the mix of information that investors can use. However, commenters other than investors did not support disclosure of auditor tenure in the auditor's report on the basis that such disclosure would not provide value to investors or could result in false conclusions about correlations between auditor tenure and audit quality or between auditor tenure and auditor independence. Many of these commenters recommended that, if the Board determined to require disclosure of auditor tenure, it should be disclosed in Form AP rather than in the auditor's report as a means of avoiding these inferences.

Alternatives Considered, Including Policy Choices Under the Final Standard

After considering the comments received, the Board is adopting a new

¹⁴⁷ See, e.g., Joseph V. Carcello and Albert L. Nagy, *Audit Firm Tenure and Fraudulent Financial Reporting*, 23 *Auditing: A Journal of Practice & Theory* 55, 55-69 (2004) and Timothy B. Bell, Monika Causholli, and W. Robert Knechel, *Audit Firm Tenure, Non-Audit Services, and Internal Assessments of Audit Quality*, 53 *Journal of Accounting Research* 461, 461-509 (2015).

¹⁴⁸ See, e.g., Larry R. Davis, Billy S. Soo, and Gregory M. Trompeter, *Auditor Tenure and the Ability to Meet or Beat Earnings Forecasts*, 26 *Contemporary Accounting Research* 517, 517-548 (2009).

¹⁴⁹ See, e.g., Mai Dao, Suchismita Mishra, and K. Raghunandan, *Auditor Tenure and Shareholder Ratification of the Auditor*, 22 *Accounting Horizons* 297, 297-314 (2008).

auditor reporting standard, AS 3101 and related amendments to its standards. The final standard retains the pass/fail model while expanding auditor reporting to include the communication of critical audit matters. Investor commenters have consistently asked for additional information in the auditor's report to make it more informative about the audit of the company's financial statements.

As described below, the Board has considered a number of alternative approaches to achieve the potential benefits of enhanced auditor reporting.

Alternatives Raised by Commenters

Only Cross-Reference to Management's Disclosures

Some commenters suggested that, instead of communicating critical audit matters as reproposed, auditors should only identify the critical audit matters and provide a cross-reference to management disclosures (*i.e.*, not describe the principal considerations that led the auditor to determine a matter is a critical audit matter or how it was addressed in the audit), or refer to or list critical accounting policies and estimates as disclosed by management. The Board believes that communicating the principal considerations that led the auditor to determine that a matter is a critical audit matter and how it was addressed in the audit will provide useful information beyond simply referencing existing management disclosure, and is more responsive to investor requests for more information from the auditor's perspective.

Auditor Association With Other Company Disclosures

Other commenters suggested more specific auditor assurance on particular management disclosures, such as inclusion of a statement in the auditor's report that the audit included evaluation of the accounting policies and significant estimates, with a cross-reference to management's disclosures, or a statement of auditor concurrence with the critical accounting policies and estimates of the company. One commenter suggested that audit committees should disclose critical audit matters with a corresponding confirmation from the independent auditor.

Several commenters on the proposal also suggested that the Board should consider auditor association with, or attestation on, portions of MD&A, specifically management's critical accounting policies and estimates, as an alternative to expanded auditor reporting. These commenters have

argued that such an association could increase the quality and reliability of the information subject to the procedures.

Some commenters on the concept release, including investors, said that they were not supportive of separate assurance by the auditor on information outside of the financial statements as an alternative to expanded auditor reporting, primarily because the related auditor reporting would have appeared in a standardized form and would not provide audit-specific information. Requiring such reporting might necessitate action by the SEC, as well as the PCAOB, to implement, including new SEC rules regarding management reporting and auditor attestation. In addition to reporting requirements, the PCAOB might have to develop new performance requirements and auditors would be required to undertake additional audit work in order to provide attestation in these areas.

Based on concerns about the complexity of such an approach, as well as the comments received as to its limited benefits, the Board determined not to pursue auditor association with portions of MD&A as an alternative to expanded auditor reporting at this time. The Board believes that this approach would fail to deliver the audit-specific information requested by investors, while also raising potential concerns about separate assurance on the identified matters.

No Change to Auditor Reporting Requirements

The Board considered whether changes to the existing auditor reporting requirements were needed. Auditor reporting under the current model has been criticized by many commenters as providing limited information. Auditors have not voluntarily provided more information in the auditor's report in response to investors' requests. A number of factors described above, such as potential costs and uncertainties related to voluntary auditor reporting and the potential for auditor status quo bias, may explain why voluntary reporting would not be expected to become prevalent. These factors suggest that voluntary reporting, with or without guidance to encourage it, could also create uncertainty about the content of auditor's reports because auditors would be able to choose whether to provide information about the audit, what information to provide, and the form in which to provide it. On that basis, the Board believes that standard setting is appropriate.

Consideration of Analogous Requirements of Other Regulators and Standard Setters

In developing the final standard, the Board took into account the requirements for expanded auditor reporting of other regulators and standard setters, such as the IAASB, the FRC, and the EU. Changes to the auditor's report that other regulators and standard setters have adopted include some commonality, such as communicating information about audit-specific matters in the auditor's report. Several commenters suggested that the Board align its requirements for expanded auditor reporting more closely with the requirements of the IAASB to provide more consistent global auditor reporting requirements.

However, the Board recognizes that the regulatory environments in other jurisdictions are different from the United States, requiring the Board to address unique U.S. requirements and characteristics in its standard-setting projects. Because the Board's standards have the force of law, the Board aims to make them as clear and easy to apply as it can. For example, the factors that the auditor considers in determining whether a matter involved especially challenging, subjective, or complex auditor judgment are included in the standard; by contrast, while the IAASB approach includes similar factors, they appear in the application and other explanatory material.

In addition, there are differences between requirements and terminology of the Board's auditing standards and those of other regulators and standard setters that may cause inconsistent application, even if the Board were to adopt the approach of another standard setter. For example, the Board's requirements for communications to the audit committee are not identical to the analogous requirements of the IAASB. Therefore, although both critical audit matters and the IAASB's key audit matters are derived from such communications, the matters ultimately discussed with the audit committee under each framework would not necessarily be the same, which could result in differences in which matters are reported even if the language in the auditor reporting standards were identical. Also, the component of the definition of critical audit matter in the final standard, namely "matters that involve especially challenging, subjective, or complex auditor judgment" grounds the definition in the auditor's expertise and judgment. Although the processes of identifying these matters vary across jurisdictions,

there are commonalities in the underlying criteria regarding matters to be communicated and the communication requirements, such that expanded auditor reporting could result in the communication of many of the same matters under the various approaches.

Auditor Assessment and Descriptions of Certain Financial Statement Areas

Several commenters on the concept release suggested that investors would be most interested in auditor reporting on the categories of information identified by investor respondents to the 2011 survey conducted by a working group of the IAG: (1) Significant management estimates and judgments made in preparing the financial statements and the auditor's assessment of them; (2) areas of high financial statement and audit risk; (3) unusual transactions, restatements, and other significant changes in the financial statements; and (4) the quality, not just the acceptability, of the company's accounting practices and policies.¹⁵⁰ This request was reiterated by several commenters on the proposal, who continued to believe that this approach would provide the information investors want most. In a similar vein, other commenters on the reproposal have requested that the auditor provide a "grade" on management's significant accounting estimates and judgments.

The Board believes that the final critical audit matter definition will likely cover many of the topic areas requested by investors. For example, the auditor may communicate critical audit matters related to significant management estimates and judgments, highlight areas of high financial statement and audit risk, and discuss significant unusual transactions. However, the auditor will not be required to report on its assessment of management's significant estimates and judgments or on the quality (as opposed to merely the acceptability), of the company's accounting practices and policies or of the financial statements as a whole.

The final standard seeks to strike an appropriate balance between the value of the information being provided and the costs of providing it. Requiring auditors to report their qualitative assessments in a manner that appears very precise (for example, describing an estimate as "conservative" or "aggressive" or assigning the financial statements an "A" or a "B") may impose significantly greater costs and unintended consequences than the

¹⁵⁰ See IAG 2011 survey.

principles-based reporting of critical audit matters. For example, although the reporting of qualitative assessments would appear to be precise, these qualitative assessments are likely to be applied inconsistently because there is no framework for such assessments and the determinations are inherently subjective. In addition, such assessments may heighten concerns related to the perceived level of assurance provided by the audit or the perception that separate assurance is being provided as to the assessed areas. Also, the reporting of such qualitative assessments may subject auditors and companies to additional litigation risk beyond what may result from the principles-based reporting of critical audit matters because the apparent precision of the reporting may facilitate plaintiffs' claims.

Policy Choices

Definition of Critical Audit Matters

The Board considered a variety of possible approaches to the definition of critical audit matters suggested by commenters. *See above* for a discussion of the Board's considerations of the final standard.

Communication of Critical Audit Matters

The Board considered a variety of possible approaches to the communication requirements for critical audit matters. *See above* for a discussion of the Board's considerations of the final standard.

Auditor Tenure

The final standard retains the repropose requirement to include a statement in the auditor's report about auditor tenure.

In the reproposal, the Board solicited comment on whether disclosure of auditor tenure should be made on Form AP instead of in the auditor's report. Form AP was developed as a means to address commenter concerns about the potential liability implications of naming persons in the auditor's report. Because the disclosure of auditor tenure does not have the same potential liability consequences, such an approach is unnecessary in this case. In addition, some commenters preferred tenure disclosure on Form AP because of a concern that disclosure in the auditor's report could result in inappropriate inferences about correlations between auditor tenure and audit quality, or between auditor tenure and auditor independence. The Board is not persuaded by such concerns. Further, the final standard allows the auditor flexibility in the location of the

auditor tenure disclosure in the auditor's report.

The Board determined that disclosure will be better achieved through the auditor's report because the information will be more readily accessible upon the filing with the SEC of a document containing audited financial statements and poses lower search costs, particularly for those investors who may prefer to have the information provided in the auditor's primary means of communication. In addition, disclosing tenure in the auditor's report will make information available earlier to investors, which may assist in their voting on auditor ratification. However, disclosing auditor tenure in the auditor's report rather than Form AP could result in higher costs to investors that wish to accumulate tenure data for a large number of companies or compare data across companies because these investors will have to acquire tenure data from each company's auditor's report separately or from a data aggregator.

Additional Improvements to the Auditor's Report

The final standard includes a number of requirements that will enhance the standardized content of the auditor's report by clarifying the auditor's role and responsibilities related to the audit of the financial statements. These include, for example, statements regarding auditor independence requirements and the addition of the phrase "whether due to error or fraud," when describing the auditor's responsibility under PCAOB standards to obtain reasonable assurance about whether the financial statements are free of material misstatements. In addition, the final standard includes requirements intended to promote uniformity in the form of the auditor's report. These include requirements as to the addressee, a specific order of certain sections of the auditor's report, and required section headings.

Many commenters generally supported these enhancements and suggested that such enhancements will increase the usability of the auditor's report by improving financial statement users' understanding of the auditor's responsibilities, reducing search costs for information in the auditor's report, and facilitating comparisons across auditor's reports.

Applicability of Critical Audit Matter Requirements

Brokers and Dealers, Investment Companies, and Benefit Plans

The repropose standard did not require communication of critical audit matters for audits of brokers and dealers reporting under Exchange Act Rule 17a-5, investment companies other than business development companies ("BDCs"), and benefit plans. The repropose release described the Board's rationale, including economic considerations, for such exclusions from the critical audit matter requirements and noted that auditors of these entities would not be precluded from including critical audit matters in the auditor's report voluntarily.

Commenters generally supported these exclusions, pointing to the same or similar reasons to those described by the Board in the repropose release. Some commenters asserted that the communication of critical audit matters should apply to all companies. One commenter supported voluntary communication of critical audit matters for the exempted entities. Another commenter disagreed with providing auditors the ability to voluntarily communicate critical audit matters for brokers and dealers and investment companies. This commenter also suggested that all broker-dealers, including broker-dealers that are issuers, should be excluded from the requirement.

After considering the comments received and evaluating benefits and costs, the final standard excludes the audits of brokers and dealers that are reporting under Exchange Act Rule 17a-5, investment companies other than BDCs, and benefit plans, from the critical audit matter requirements as repropose.¹⁵¹ Auditors of these entities may choose to include critical audit matters in the auditor's report voluntarily.

The Board's rationales for these exclusions are described below.

Brokers and Dealers Reporting Under Exchange Act Rule 17a-5

Pursuant to Exchange Act Rule 17a-5, the annual reports that brokers and dealers file with the SEC are public, except that if the statement of financial condition in the financial report is bound separately from the balance of the annual report, the balance of the annual report is deemed confidential and nonpublic.¹⁵² In this situation, the

¹⁵¹ The other requirements of the final standard will be applicable to audits of these entities.

¹⁵² *See* Exchange Act Rule 17a-5(e), 17 CFR 240.17a-5(e).

auditor would generally issue two separate auditor's reports that would have different content: (1) An auditor's report on the statement of financial condition that would be available to the public and (2) an auditor's report on the complete financial report that, except as provided in paragraph (c)(2)(iv) of Exchange Act Rule 17a-5, would be confidential and not available to the public.¹⁵³ Research by the PCAOB's Office of Economic and Risk Analysis ("ERA")¹⁵⁴ indicates that, for approximately half of brokers and dealers, the complete financial report and the related auditor's report are confidential and not available to the public.

In 2013, the Board adopted new standards related to brokers and dealers that enhanced the auditor's performance and reporting responsibilities for financial statement audits, as well as engagements on compliance and exemption reports of brokers and dealers.¹⁵⁵

Some commenters on the proposal asserted that the value of reporting critical audit matters for brokers and dealers would be significantly limited by the closely held nature of brokers and dealers; the limited number of users of their financial statements; and the fact that, in many cases, only the statement of financial condition is available publicly. Some commenters also recognized that both the SEC and PCAOB recently updated their rules to further enhance reporting by brokers and dealers and their auditors.

Research by ERA indicates that currently there are no brokers or dealers that are issuers. Rather, brokers and dealers are often owned by a holding company, an individual, or a group of individuals that holds a controlling interest. The owners of brokers and dealers are generally part of the management of the entity and therefore would have direct access to the auditor. Given that, in many cases, there is much less separation of ownership and control

in brokers and dealers than in issuers, the communication of critical audit matters would provide little information about the audit that would otherwise be unobtainable by investors.

Although there may be circumstances in which other financial statement users may benefit from reduced information asymmetry about the audits of brokers and dealers, certain aspects of broker and dealer financial reporting may limit the benefits of requiring the communication of critical audit matters. For example, while other financial statement users, such as customers of brokers and dealers, may benefit from increased information about the audit, the ability for brokers and dealers to file certain financial statements and schedules confidentially would require the auditor to identify and communicate critical audit matters that apply only to the publicly available statement of financial condition. This may reduce the value of communicating critical audit matters for brokers and dealers relative to issuers. Moreover, customers of brokers and dealers may be interested in the overall financial position of the broker or dealer but may not benefit from audit-specific information in the same way as investors in an issuer.

The communication of critical audit matters may also impose additional costs on the auditors of brokers and dealers relative to the auditors of other types of companies, as they would have to identify critical audit matters that apply exclusively to the publicly available financial information, which may be difficult in some situations.

After consideration of the ownership and reporting characteristics of brokers and dealers, the comments received on the proposal and reproposal, and the Board's recent standard-setting activities related to brokers and dealers, the Board does not believe that reporting of critical audit matters for brokers and dealers will provide meaningful information in the same way as for issuers. Therefore, the communication of critical audit matters is not required for audits of brokers and dealers reporting under Exchange Act Rule 17a-5. If a broker or dealer were an issuer required to file audited financial statements under Section 13 or 15(d) of the Exchange Act, the requirements would apply.

Investment Companies

The Investment Company Act generally defines an investment company as any issuer that is engaged primarily in the business of investing, reinvesting, or trading in

securities.¹⁵⁶ Most investment companies registered under the Investment Company Act are required to file with the SEC annual reports on Form N-CSR containing audited financial statements.¹⁵⁷ The Investment Company Act includes specific requirements for investment companies, intended to reduce investors' risks, in areas such as an investment company's portfolio diversification, liquidity, leverage, and custody of securities.¹⁵⁸

In an SEC rulemaking, the SEC observed that commenters believed the key information that investors use in deciding to invest in an investment company includes an investment company's investment objectives, strategies, risks, costs, and performance.¹⁵⁹ The disclosure of information about these items appears in the annual prospectus that investment companies provide to current and future investors.¹⁶⁰ Changes to investment objectives and strategies require shareholder approval or disclosure.¹⁶¹

Several commenters on the proposal noted that an investor's decision to invest in an investment company is primarily based on the investment objectives, risks, performance, and fees, and critical audit matters are not expected to provide information about these items and therefore would not be relevant. These and other commenters generally stated that investment companies are designed for the sole purpose of trading in and holding investments and auditor judgment would arise primarily with respect to valuation of investments, which would tend to be repeated as a critical audit matter. One of these commenters noted that, since the strategies of investment companies do not change significantly over time, the critical audit matters identified could become standardized from one reporting period to the next and also across funds with similar objectives.

Even though the disclosures required under the Investment Company Act and

¹⁵³ See also Exchange Act Rule 17a-5(c)(2), 17 CFR 240.17a-5(c)(2), regarding audited statements required to be provided to customers.

¹⁵⁴ ERA's research was conducted on brokers and dealers who filed financial statements through May 15, 2015, for fiscal years ended during 2014 that included audit reports issued by firms registered with the PCAOB.

¹⁵⁵ See *Attestation Standards for Engagements Related to Broker and Dealer Compliance or Exemption Reports Required by the U.S. Securities and Exchange Commission and Related Amendments to PCAOB Standards*, PCAOB Release No. 2013-007 (Oct. 10, 2013) and *Auditing Standard No. 17, Auditing Supplemental Information Accompanying Audited Financial Statements and Related Amendments to PCAOB Standards*, PCAOB Release No. 2013-008 (Oct. 10, 2013).

¹⁵⁶ See Section 3(a)(1) of the Investment Company Act.

¹⁵⁷ See SEC Rules under Section 30(e) of the Investment Company Act.

¹⁵⁸ See, e.g., Sections 12, 13, and 17 of the Investment Company Act.

¹⁵⁹ See SEC, *Enhanced Disclosure and New Prospectus Delivery Option for Registered Open-End Management Investment Companies*, Securities Act Release No. 8998, 74 FR 4546 (Jan. 26, 2009). See also Investment Company Institute, *Understanding Investor Preferences for Mutual Fund Information* (Aug. 2006) at 2-3.

¹⁶⁰ See SEC Rules under Section 30(e) of the Investment Company Act.

¹⁶¹ See Sections 8(b) and 13(a)(3) of the Investment Company Act and Investment Company Act Rule 8b-16.

other federal securities laws provide investors with useful information, they may not fully substitute for the communication of critical audit matters. The required communication of critical audit matters contemplates that auditors would provide investors with audit-specific information, which is unlikely to appear in the disclosures provided by management. In addition, some academic research documented a difference in the perceived usefulness and reliability of information depending on the location of the disclosure and whether it was disclosed by management or by the independent auditor.¹⁶² This academic research suggests that the auditor's communication of information similar to critical audit matters may provide value to investors because it comes from the auditor, even if the same information is disclosed by management in the experimental design of the study.

The benefits of providing critical audit matters, however, may be smaller for investment companies, other than BDCs, relative to other types of companies because of their purpose and structure. Unlike companies whose business models can change over time, investment companies have specific investment mandates that are disclosed in the prospectus and rarely change. This creates the potential for critical audit matters of investment companies to become excessively repetitive, making them uninformative.

There may also be additional costs of applying critical audit matter requirements to audits of investment companies, other than BDCs, as compared to audits of other types of companies. For example, in some cases, annual shareholder reports of affiliated investment companies with the same fiscal year-end might be filed with the SEC in one document, which generally contains a single auditor's report that covers multiple audited investment companies. In these situations, communicating critical audit matters specific to each investment company may require the auditor to prepare separate auditor's reports. This could increase costs for these types of investment companies.

After consideration of the purpose and reporting characteristics of investment companies and the comments received on the proposal and reproposal, the Board has determined not to require the communication of critical audit matters for audits of most investment companies, although they

will apply to audits of investment companies regulated as BDCs.¹⁶³ Unlike the audits of many other investment companies, auditing the valuation of BDCs' investments generally involves complexity and auditor judgments due to the nature of the BDCs' portfolios. Also, because of the more diverse operations of BDCs, such as providing managerial assistance and involvement with more complex debt and equity instruments than other investment companies, communication of critical audit matters in a BDC audit could be more informative to investors. Additionally, BDCs follow a reporting regime under the Exchange Act that is more closely aligned with that of companies to which the Board is applying the requirements for critical audit matters. For these reasons, the Board believes it is appropriate for audits of BDCs to be subject to critical audit matter requirements.

Benefit Plans

Benefit plans that purchase and hold securities of the plan sponsor using participants' contributions are generally required to file with the SEC an annual report on Form 11-K¹⁶⁴ that includes the benefit plan's audited financial statements and the related auditor's report.¹⁶⁵ The audit of the financial statements included in a filing on Form 11-K is performed in accordance with the standards of the PCAOB. Benefit plans are also generally subject to the financial reporting requirements of the Employee Retirement Income Security Act of 1974 ("ERISA"), including the U.S. Department of Labor's ("DOL") rules and regulations for disclosure under ERISA.¹⁶⁶

Participation in a benefit plan is limited to eligible employees of the plan sponsor. Each plan participant in a defined contribution benefit plan is responsible for selecting, from the investment options made available by the plan sponsor, the specific investments in which the participant's funds are invested.

Employee stock benefit plans are generally less complex than other types

of companies because they are designed for the sole purpose of holding the plan's investments for the participants' benefit. A plan's financial statements reflect summary information about the plan's assets and liabilities by aggregating the balances of all plan participants. However, only the individual account statements that plan participants receive periodically provide information specific to each participant's investments.

Several commenters on the proposal suggested excluding audits of benefit plans from the requirement for reporting critical audit matters due to the unique characteristics of these entities and their differences from other types of companies. For example, some commenters indicated that benefit plans are designed for a specific purpose and, as a result, would likely have similar critical audit matters from one reporting period to the next. Other commenters noted that benefit plans are inherently less complex and entail fewer estimates and judgments.

The communication of critical audit matters could provide information about any complex issues that were identified during the audit and how the auditor addressed them. However, since a benefit plan's assets and liabilities aggregate the balances of all plan participants, the financial statements or related critical audit matters would not provide actionable information about a plan participant's specific investment. Further, given the nature of benefit plans, there is a chance that the same critical audit matters would be communicated each year. For example, the valuation of investments is likely to be the most complex area in the audit of a benefit plan and therefore may be a critical audit matter in each reporting period, making the information less useful.

After consideration of the structure and reporting characteristics of benefit plans and the comments received on the proposal and reproposal, the Board has determined not to require the communication of critical audit matters for audits of benefit plans.

Smaller Companies

The reproposal sought comment on whether the critical audit matter requirements should not apply to audits of other types of companies, in addition to the exempted entities discussed above. Some commenters asserted that the communication of critical audit matters should apply to all companies. Other commenters recommended that the Board give consideration to not applying the critical audit matter requirements to audits of smaller

¹⁶² See, e.g., Christensen et al., *Do Critical Audit Matter Paragraphs in the Audit Report Change Nonprofessional Investors' Decision to Invest?*

¹⁶³ See Section 54 of the Investment Company Act.

¹⁶⁴ See Section 15(d) of the Exchange Act.

¹⁶⁵ A benefit plan's audited financial statements may also be included as part of the annual report of the issuer sponsoring the benefit plan. See Exchange Act Rule 15d-21, CFR 240.15d-21.

¹⁶⁶ ERISA Section 103(a)(3)(A) requires a plan administrator to engage an independent auditor to conduct an examination of the plan's financial statements and required schedules in accordance with generally accepted auditing standards. See 29 CFR 2520.103-1. Benefit plans subject to ERISA also file with the DOL an annual report on Form 5500, including audited financial statements and an auditor's report. See also FASB ASC 960-10-05-6.

reporting companies¹⁶⁷ and nonaccelerated filers¹⁶⁸ due to their smaller size and because, in the commenters' view, communication of critical audit matters would not provide sufficient benefits for these companies to justify the costs.

Academic research suggests that smaller companies have a higher degree of information asymmetry relative to the broader population of companies. Although the degree of information asymmetry surrounding a particular issuer is unobservable, researchers have developed a number of proxies that are thought to be correlated with information asymmetry, including small issuer size, lower analyst coverage, larger insider holdings, and higher research and development costs.¹⁶⁹ To the extent that a smaller company can be characterized as exhibiting one or more of these properties, this may suggest that it has a greater degree of information asymmetry relative to the broader population of companies. This would suggest that there is a higher likelihood that critical audit matters could provide new information about a smaller company than a large one for which there already exists a variety of information sources (such as annual reports, news media, and analyst research reports).

After consideration of comments, academic research, and data regarding the number of such companies, the final standard does not exclude smaller companies from the critical audit matter requirements. However, as discussed

below, the Board has determined that it is appropriate to give auditors of smaller companies additional time to implement the new requirements. If approved by the SEC, auditors of companies that are not large accelerated filers will have an additional 18 months to implement the requirements for critical audit matters and will be able to benefit from the experiences of auditors of larger companies.

Requirements of Other Regulators and Standard Setters

Under the IAASB's standard, the communication of key audit matters applies to listed entities.¹⁷⁰ The EU requirements apply to audits of PIEs, including listed companies, credit institutions, and insurance companies.¹⁷¹ The FRC 2013 requirements apply to auditor's reports for entities that apply the UK Corporate Governance Code.¹⁷²

Considerations for Audits of Emerging Growth Companies

Section 104 of the Jumpstart Our Business Startups ("JOBS") Act imposes certain limitations with respect to application of the Board's standards to audits of EGCs, as defined in Section 3(a)(80) of the Exchange Act. Section 104 provides that "[a]ny rules of the Board requiring . . . a supplement to the auditor's report in which the auditor would be required to provide additional information about the audit and the financial statements of the issuer (auditor discussion and analysis) shall not apply to an audit of an emerging growth company . . ." ¹⁷³ Auditor discussion and analysis ("AD&A") does not exist in auditing standards. The idea was introduced in the concept release, which described AD&A as one of several conceptual alternatives for changing the auditor's reporting model.¹⁷⁴

Section 104 of the JOBS Act further provides that any additional rules adopted by the Board subsequent to

April 5, 2012, do not apply to the audits of EGCs unless the SEC "determines that the application of such additional requirements is necessary or appropriate in the public interest, after considering the protection of investors, and whether the action will promote efficiency, competition, and capital formation." ¹⁷⁵ As a result of the JOBS Act, the final standard and amendments are subject to an evaluation as to whether they could, and if so, should be applicable to the audits of EGCs.

Critical Audit Matters

The reproposal solicited comment on the application of critical audit matter requirements to the audits of EGCs. Commenters on this issue generally favored applying the standard to audits of EGCs, primarily because investors in these companies would benefit from the additional information communicated in the auditor's report in the same way that investors in larger companies would. Two commenters recommended that the critical audit matter requirements not apply to audits of EGCs because there would not be sufficient benefits to justify the costs.

Three commenters addressed the legal question of whether the JOBS Act provision on AD&A would prohibit the Board from applying critical audit matter requirements to audits of EGCs. Two of these commenters suggested that this would be prohibited, on the basis that critical audit matters "appear substantively similar to" ¹⁷⁶ or "closely resemble" ¹⁷⁷ AD&A. The SEC's Investor Advocate stated that, from a policy perspective, critical audit matter requirements should apply to audits of EGCs, and recommended that the PCAOB adopt the standard for policy reasons and let the SEC determine the legal question.¹⁷⁸ This commenter also recommended that, "to prepare for any outcome of the SEC's determination," the PCAOB should encourage auditors, on a voluntary basis, to include critical audit matter communications in the auditor's reports on EGCs." ¹⁷⁹

The requirements for critical audit matters share characteristics with two of

¹⁶⁷ In general, a "smaller reporting company" means an issuer with less than \$75 million in public float or zero public float and annual revenues of less than \$50 million during the most recently completed fiscal year for which audited financial statements are available. See Exchange Act Rule 12b-2, 17 CFR 240.12b-2. Smaller reporting companies currently make up approximately 42 percent of Form 10-K filers. The SEC recently proposed changes to the definition of smaller reporting companies, which would increase the percentage of smaller reporting companies to approximately 52 percent of Form 10-K filers. See SEC, *Amendments to Smaller Reporting Company Definition*, Release No. 33-10107 (June 27, 2016), 81 FR 43130 (July 1, 2016).

¹⁶⁸ Nonaccelerated filers are not defined in SEC rules but are generally understood to be companies that do not meet the definition of large accelerated filer or accelerated filer.

¹⁶⁹ See, e.g., David Aboudy, and Baruch Lev, *Information Asymmetry, R&D, and Insider Gains*, 55 *The Journal of Finance* 2747, 2747-2766 (2000), Michael J. Brennan and Avandhar Subrahmanyam, *Investment Analysis and Price Formation in Securities Markets*, 38 *Journal of Financial Economics* 361, 361-381 (1995), Varadarajan V. Chari, Ravi Jagannathan, and Aharon R. Ofer, *Seasonalities in Security Returns: The Case of Earnings Announcements*, 21 *Journal of Financial Economics* 101, 101-121 (1988), and Raymond Chiang, and P.C. Venkatesh, *Insider Holdings and Perceptions of Information Asymmetry: A note*, 43 *The Journal of Finance* 1041, 1041-1048 (1988).

¹⁷⁰ See paragraph 5 of ISA 701.

¹⁷¹ See requirements in 1 of Article 2, Audit Report of Regulation (EU) No 537/2014.

¹⁷² These include companies with a premium listing of equity shares on the London Stock Exchange regardless of whether they are incorporated in the U.K. or elsewhere.

¹⁷³ See Public Law 112-106 (Apr. 5, 2012). See Section 103(a)(3)(C) of Sarbanes-Oxley, as added by Section 104 of the JOBS Act.

¹⁷⁴ See PCAOB Release No. 2011-003 (June 21, 2011) at 2 (describing one alternative as "a supplement to the auditor's report in which the auditor would be required to provide additional information about the audit and the company's financial statements (an 'Auditor's Discussion and Analysis')"). Section IV.A., Auditor's Discussion and Analysis, of the proposal further described AD&A and related comments received on the concept release.

¹⁷⁵ See Section 103(a)(3)(C) of Sarbanes-Oxley.

¹⁷⁶ See letter from the U.S. Chamber of Commerce, Center for Capital Markets Competitiveness (Aug. 15, 2016) at 10, available on the Board's Web site in Docket 034.

¹⁷⁷ See letter from Robert N. Waxman (Aug. 15, 2016) at 24, available on the Board's Web site in Docket 034.

¹⁷⁸ See letter from Rick A. Fleming, Investor Advocate, SEC (Aug. 15, 2016) at 5-6, available on the Board's Web site in Docket 034 (noting that "the SEC will need to make a legal determination on whether such a requirement with respect to the audits of EGCs would accord with certain provisions of" the JOBS Act).

¹⁷⁹ 179 Id. at 6.

the alternative approaches described in the concept release: Required and expanded explanatory paragraphs and AD&A. Similar to critical audit matters, required and expanded explanatory paragraphs involved additional paragraphs in the auditor's report that would have highlighted areas of critical importance to the financial statements, with auditor comment on key audit procedures and a reference to relevant financial statement accounts and disclosure. AD&A, by contrast, envisioned a supplemental report in addition to the auditor's report that could cover a broad range of issues, including the auditor's views regarding the company's financial statements, material matters as to which the auditor believed disclosure could be enhanced, and areas where management could have applied different accounting or disclosure approaches.

However, critical audit matters go beyond the content of a required and expanded explanatory paragraph by including a discussion of the principal reasons the auditor determined that a matter was a critical audit matter. Further, although this is not required, critical audit matters could potentially include a discussion of auditor findings. These additional elements may make critical audit matters resemble AD&A in some respects. This potential similarity, together with the fact that there has been no authoritative interpretation of Section 104 of the JOBS Act, creates some uncertainty as to whether it is legally permissible for critical audit matter requirements to be mandated for EGC audits. In view of this uncertainty, the Board has determined not to apply the requirements regarding critical audit matters to audits of EGCs at this time.

As with other audits where critical audit matter requirements do not apply, voluntary application is permissible. EGCs and their auditors can consider whether investors would benefit from additional information about the audit from the auditor's point of view.

Additional Improvements to the Auditor's Report

The additional improvements to the auditor's report contained in the final standard and amendments do not raise concerns under the AD&A provisions of the JOBS Act, but instead fall within the category of "additional rules" that may not be applied to audits of EGCs unless the SEC determines that doing so "is necessary or appropriate in the public interest, after considering the protection of investors, and whether the action will promote efficiency, competition, and capital formation." The Board is

providing this analysis to assist the SEC in making this determination.

To inform consideration of the application of auditing standards to audits of EGCs, the staff has also published a white paper that provides general information about characteristics of EGCs.¹⁸⁰ The data on EGCs outlined in the white paper remains generally consistent with the data discussed in the reproposal. A majority of EGCs continue to be smaller public companies that are generally new to the SEC reporting process. This suggests that there is less information available to investors regarding such companies (a higher degree of information asymmetry) relative to the broader population of public companies because, in general, investors are less informed about companies that are smaller and newer. For example, smaller companies have very little, if any, analyst coverage which reduces the amount of information made available to financial statement users and therefore makes markets less efficient.¹⁸¹

The reproposal solicited comment on whether the elements of the reproposed standard and amendments other than the requirements for critical audit matters should apply to the audits of EGCs. As noted above, one commenter supported application of the entire standard and amendments to EGCs (without differentiating between critical audit matters and other elements), and one commenter opposed application of the entire standard and amendments. In addition, one commenter supported applying some of the reproposed improvements to the auditor's report to audits of EGCs (the requirement as to addressee and the clarifications of existing auditor responsibilities, as well as a modified version of the statement regarding auditor independence), but generally opposed the other aspects of the reproposal for both EGCs and other companies.

As described above, the additional improvements to the auditor's report are intended to provide a consistent location and decrease search costs with respect to information about auditor tenure, enhance users' understanding of the auditor's role, make the auditor's report easier to read and facilitate comparison across companies by making the format consistent. As

described above, the costs associated with these changes are not expected to be significant and are primarily one-time, rather than recurring, costs.

For the reasons explained above, the Board believes that the additional improvements to the auditor's report contained in the final standard and amendments are in the public interest and, after considering the protection of investors and the promotion of efficiency, competition, and capital formation, recommends that the final standard and amendments should apply to audits of EGCs. Accordingly, the Board recommends that the SEC determine that it is necessary or appropriate in the public interest, after considering the protection of investors and whether the action will promote efficiency, competition, and capital formation, to apply the final standard and amendments, other than the provisions relating to critical audit matters, to audits of EGCs. The Board stands ready to assist the SEC in considering any comments the SEC receives on these matters during the SEC's public comment process.

III. Date of Effectiveness of the Proposed Rules and Timing for Commission Action

Pursuant to Section 19(b)(2)(A)(ii) of the Exchange Act, and based on its determination that an extension of the period set forth in Section 19(b)(2)(A)(i) of the Exchange Act is appropriate in light of the PCAOB's request that the Commission, pursuant to Section 103(a)(3)(C) of the Sarbanes-Oxley Act, determine that the proposed rules, other than the provisions relating to critical audit matters, apply to audits of emerging growth companies, as defined in Section 3(a)(80) of the Exchange Act, the Commission has determined to extend to October 26, 2017 the date by which the Commission should take action on the proposed rules.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rules are consistent with the requirements of Title I of 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/pcaob.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number PCAOB-2017-01 on the subject line.

¹⁸⁰ See *White Paper on Characteristics of Emerging Growth Companies as of November 15, 2016* (Mar. 28, 2017), available on the Board's Web site in Docket 034.

¹⁸¹ See SEC, *Final Report of the Advisory Committee on Smaller Public Companies to the U.S. Securities and Exchange Commission* (Apr. 23, 2006) at 73.

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 PCAOB–2017–01. 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 Web site (<http://www.sec.gov/rules/pcaob.shtml>). Copies of the submission, all subsequent amendments, all written statements

with respect to the proposed rules that are filed with the Commission, and all written communications relating to the proposed rules between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing will also be available for inspection and copying at the principal office of the PCAOB. All comments received will be posted without charge; we do not edit personal

identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number PCAOB–2017–01 and should be submitted on or before August 18, 2017.

For the Commission, by the Office of the Chief Accountant, by delegated authority.¹⁸²

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–15718 Filed 7–27–17; 8:45 am]

BILLING CODE 8011–01–P

¹⁸² 17 CFR 200.30–11(b)(1) and (3).

Reader Aids

Federal Register

Vol. 82, No. 144

Friday, July 28, 2017

CUSTOMER SERVICE AND INFORMATION

Federal Register/Code of Federal Regulations

General Information, indexes and other finding aids **202-741-6000**

Laws **741-6000**

Presidential Documents

Executive orders and proclamations **741-6000**

The United States Government Manual **741-6000**

Other Services

Electronic and on-line services (voice) **741-6020**

Privacy Act Compilation **741-6050**

Public Laws Update Service (numbers, dates, etc.) **741-6043**

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: www.fdsys.gov.

Federal Register information and research tools, including Public Inspection List, indexes, and Code of Federal Regulations are located at: www.ofr.gov.

E-mail

FEDREGTOC (Daily Federal Register Table of Contents Electronic Mailing List) is an open e-mail service that provides subscribers with a digital form of the Federal Register Table of Contents. The digital form of the Federal Register Table of Contents includes HTML and PDF links to the full text of each document.

To join or leave, go to <https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new>, enter your email address, then follow the instructions to join, leave, or manage your subscription.

PENS (Public Law Electronic Notification Service) is an e-mail service that notifies subscribers of recently enacted laws.

To subscribe, go to <http://listserv.gsa.gov/archives/publaws-l.html> and select *Join or leave the list (or change settings)*; then follow the instructions.

FEDREGTOC and **PENS** are mailing lists only. We cannot respond to specific inquiries.

Reference questions. Send questions and comments about the Federal Register system to: fedreg.info@nara.gov

The Federal Register staff cannot interpret specific documents or regulations.

CFR Checklist. Effective January 1, 2009, the CFR Checklist no longer appears in the Federal Register. This information can be found online at <http://bookstore.gpo.gov/>.

FEDERAL REGISTER PAGES AND DATE, JULY

30721-30946.....	3	33439-33774.....	20
30947-31240.....	5	33775-34250.....	21
31241-31428.....	6	34251-34382.....	24
31429-31714.....	7	34383-34596.....	25
31715-31886.....	10	34597-34834.....	26
31887-32122.....	11	34835-35056.....	27
32123-32226.....	12	35057-35434.....	28
32227-32446.....	13		
32447-32612.....	14		
32613-32760.....	17		
32761-32986.....	18		
32987-33438.....	19		

CFR PARTS AFFECTED DURING JULY

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

2 CFR

Proposed Rules:

Ch. VI.....32493

3 CFR

Proclamations:

9626.....33437

9627.....33769

Executive Orders:

12675 (Superseded by
EO 13803)

13761 (Amended by
13804).....32611

13803.....31429

13804.....32611

13805.....34383

13806.....34597

Administrative Orders:

Memorandums:

Memorandum of June
29, 2017.....31237

Memorandum of June
29, 2017.....31239

Notices:

Notice of July 19,
2017.....33773

Notice of July 20,
2017.....34249

5 CFR

1800.....32447

Proposed Rules:

630.....32263

6 CFR

5.....32613

1001.....34835

1003.....34835

Proposed Rules:

5.....34884

7 CFR

205.....31241

956.....31244

984.....33775

Proposed Rules:

Subtitles A.....32649

Subtitles B.....32649

986.....33829

8 CFR

103.....31887

212.....31887

214.....32988

274a.....31887

9 CFR

557.....30721

Proposed Rules:

Ch. I.....32649

Ch. II.....32649

Ch. III.....32649

10 CFR

50.....32934

72.....31433, 34387

170.....33000

171.....33000

429.....31890, 32227

430.....32227

431.....31808, 31890

1703.....30722

Proposed Rules:

72.....31512

429.....34427

431.....34427

12 CFR

1024.....30947

1026.....30947

1040.....33002, 33004, 33007

1101.....30724

1223.....34388

Proposed Rules:

704.....30774

930.....30776

932.....30776

1003.....33455

1277.....30776

1282.....31009, 31514

14 CFR

1.....34397

13.....31440

23.....32614, 32616, 32618

25.....35057

39.....30949, 30953, 30955,

30958, 30961, 31245, 31250,

31892, 31899, 31901, 32447,

32620, 32622, 32626, 32629,

33002, 33004, 33007, 33439,

33778, 33780, 33782, 33785,

33787, 34251, 34257, 34259,

34838, 34841, 34844, 34846

63.....34397

71.....30964, 31440, 32450,

33790, 33791, 33792, 33794,

33795, 33796, 33798, 35057,

35058, 35060, 35061

97.....32228, 32230

121.....34397

125.....34397

135.....34397

147.....34397

170.....34397

1264.....32123

1271.....32123

Proposed Rules:

23.....30798

33.....30800

39.....30802, 31535, 32494,

32496, 32498, 32501, 32503,

32507, 32650, 32652, 32654,

32656, 32658, 33465, 34449,

34453, 34885, 34888, 34891,
35127
71 31030, 31031, 31033,
31034, 32149, 32151, 33833,
33834, 33836, 33837, 34272,
35129, 35131
73 30805

15 CFR

742 31442
744 31442
772 31442
774 31442

Proposed Rules:

801 34894
2301 32776

16 CFR

1 30966
803 32123

Proposed Rules:

1245 31035

17 CFR

232 35062

Proposed Rules:

230 33839

18 CFR**Proposed Rules:**

1318 35133

19 CFR

4 32232
10 32232
12 32452
18 32232
113 32232
122 32232
123 32232
141 32232
159 35064
181 35064
191 32232
192 32232

Proposed Rules:

24 32661
101 30807, 32669
111 32661

20 CFR

404 34400
416 34400
655 32988

21 CFR

1 30730
11 30730, 34401
17 34402
73 30731
101 30730, 34401
866 34848
870 34850, 35065
876 35067
882 35069
884 35071
1308 32453
1310 32457

Proposed Rules:

172 34615
573 34615
1308 32153

22 CFR

147 34852

Proposed Rules:

Ch. I 32493
1305 35134

24 CFR

982 32461, 32463
983 32461, 32463

Proposed Rules:

3280 34898
3282 34898
3285 34898
3286 34898

25 CFR

515 34402

26 CFR

1 33441, 34601
31 33441
51 34611
300 33009

Proposed Rules:

1 32281, 33467, 34456
31 33467

28 CFR**Proposed Rules:**

Ch. XI 32493

29 CFR

1910 31252
4022 32463

Proposed Rules:

541 34616
2509 31278
2510 31278
2550 31278
Ch. XL 34619

30 CFR

938 31715

31 CFR**Proposed Rules:**

1010 31537

32 CFR

706 30967, 31717

Proposed Rules:

644 33470

33 CFR

3 35073
20 35073
64 35073
67 35073
80 35073
82 35073
83 35073
84 35073
100 31449, 31903, 32135,
32241, 33799, 34853, 35093,
35094
104 35073
105 35073
109 35073
110 35073
115 35073
117 30735, 30736, 30968,
31253, 31254, 31255, 31906,
31907, 32464, 32761, 33448,
33799, 33802, 34404, 34853,
84854, 35073, 35094

120 35073

133 35073

135 35073
136 35073
137 35073
138 35073
147 33799
151 35073
155 35073
157 35073
159 35073
161 35073
162 35073
164 35073

165 30736, 30739, 30741,
30743, 30745, 30969, 30971,
30973, 31255, 31257, 31260,
31450, 31452, 31454, 31455,
31719, 31903, 31908, 32135,
32242, 32244, 32246, 32247,
32465, 32467, 32469, 32472,
32632, 32634, 33449, 33451,
33799, 33803, 34261, 34404,
34405, 34407, 34612, 34855,
34857, 34858, 35073, 35095,
35097, 35099

174 35073
181 35073

Proposed Rules:

Ch. I 31545, 31928, 32510,
32513, 32514, 32515, 32779,
34620, 34909
100 31733
117 31036, 32157, 32777
165 35136, 35138
Ch. II 33470
328 34899

34 CFR

104 31910
105 31910
200 31690
222 31910
299 31690
300 31910
361 31910
373 31910
385 31910
668 30975, 31910, 32762
674 31910

36 CFR**Proposed Rules:**

312 33470
327 33470
328 33470
330 33470
331 33470

37 CFR

2 33804

38 CFR

17 34408
74 32137

Proposed Rules:

4 35140
61 34457

39 CFR

233 32474
265 30798, 32766
447 33806
3020 32636

Proposed Rules:

3010 31736
3050 31929, 31930

40 CFR

52 30747, 30749, 30758,
30767, 30770, 30976, 31457,
31458, 31462, 31464, 31722,
31913, 31916, 32474, 32480,
32641, 32644, 32762, 32771,
33012, 33014, 33807, 35101,
35104, 35106

60 32644
61 32644
63 34858
80 32779, 32780
81 30976, 31722
82 33809
141 34861
180 30979, 30982, 30987,
30990, 30993, 31468, 31471,
31722, 32482, 34870, 34875,
34877, 35109, 35115, 35120
271 32249, 32253
300 31263, 32646
441 30997
702 33726, 33753
770 31267, 31922

Proposed Rules:

50 34791
52 30809, 30812, 30814,
30815, 31546, 31547, 31736,
31739, 31741, 31931, 32282,
32284, 32287, 32294, 32517,
32669, 32671, 32673, 32782,
33026, 33028, 33030, 33032,
33471, 33851, 35148, 35149,
35153

62 32301
63 34910
80 32783, 34206
110 34899
112 34899
116 34899
117 34899
122 34899
230 34899
232 34899
261 32519
271 32303, 32304, 32305
300 31281, 34899
302 34899
401 34899
770 31932

41 CFR**Proposed Rules:**

51-11 33852

42 CFR

71 31728
405 32256
409 31729, 32256
410 31729
418 31729
424 35122
431 31158, 32256
440 31729
447 32256
457 31158
482 32256
483 32256
484 31729
485 31729, 32256
488 31729, 32256
489 32256

Proposed Rules:

88 32312
405 33950
409 35270

410.....33950
 413.....31190
 414.....31190, 33950
 416.....33558
 419.....33558
 424.....33950
 425.....33950
 447.....35155
 484.....35270

43 CFR

8360.....31268

Proposed Rules:

3160.....34464

44 CFR

64.....33453

46 CFR

Ch. I.....32488
 4.....35073
 28.....35073
 31.....35073
 39.....35073
 44.....35073
 50.....35073
 58.....35073

63.....35073
 69.....35073
 71.....35073
 91.....34882
 107.....35073
 110.....35073
 111.....35073
 116.....35073
 120.....35073
 127.....35073
 153.....35073
 154.....35073
 161.....35073
 162.....35073
 170.....35073
 177.....35073
 182.....35073
 189.....35073

Proposed Rules:

Ch. I.....31545, 31928, 32510,
 32511, 32513, 32514, 32515,
 32779, 32780, 34620, 34909
 Ch. III.....31545, 31928, 32510,
 32514, 32515, 32779, 32780,
 34620, 34909

47 CFR

1.....32260, 33825
 25.....32260
 36.....32489
 73.....32260, 33825
 74.....32260, 33825
 90.....31270

Proposed Rules:

1.....31282
 32.....31282
 64.....31743, 33856, 34471,
 34911
 65.....31282

48 CFR

1501.....33016
 1504.....33016
 1509.....33016
 1515.....33016
 1516.....33016
 1517.....33016
 1519.....33016
 1535.....33016
 1552.....33016
 1553.....33016
 1816.....34416
 1852.....34416

Proposed Rules:

6.....32493

49 CFR

269.....31476
 578.....32139, 32140
 1152.....30997
 1300.....31271

Proposed Rules:

Ch. IV.....31545, 31928, 32510,
 32511, 32513, 32514, 32515,
 32779, 32780, 34620, 34909

50 CFR

20.....34751
 21.....34419
 92.....34263
 622.....31489, 31924, 34573,
 34583
 635.....32490
 648.....31491, 32145, 33827
 660.....31494
 679.....31925, 32262, 33024,
 35125, 35126

Proposed Rules:

17.....33035
 648.....33036

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 June 30, 2017

Public Laws Electronic Notification Service (PENS)

PENS is a free electronic mail notification service of newly

enacted public laws. To subscribe, go to <http://listserv.gsa.gov/archives/publaws-l.html>

Note: This service is strictly for E-mail notification of new laws. The text of laws is not available through this service. **PENS** cannot respond to specific inquiries sent to this address.