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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.

NATIONAL MEDIATION BOARD

5 CFR Chapter CI

[Docket No. C–7188]

RIN 3209–AA47

Supplemental Standards of Ethical Conduct for Employees of the National Mediation Board

AGENCY: National Mediation Board.

ACTION: Interim final rule with request for comments.

SUMMARY: The National Mediation Board (NMB or Board), with the concurrence of the U.S. Office of Government Ethics (OGE), is issuing an interim final regulation for employees of the NMB that supplements the executive branch-wide Standards of Ethical Conduct (Standards) issued by OGE. The supplemental regulation requires NMB employees to obtain approval before engaging in outside employment.

DATES: This interim final rule is effective November 1, 2018. Comments must be received on or before December 31, 2018.

ADDRESSES: You may submit comments identified by Docket Number C–7188 by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Agency Website: www.nmb.gov.* Follow the instructions for submitting comments.
- *Email: legal@nmb.gov.* Include docket number in the subject line of the message.
- *Fax:* (202) 692–5085.
- *Mail and Hand Delivery:* National Mediation Board, 1301 K Street NW, Ste. 250E, Washington, DC 20005.

Instructions: All submissions received must include the agency name and docket number. All comments received will be posted without change to *www.nmb.gov,* including any personal information provided.

Docket: For access to the docket or to read background documents or comments received, go to *www.nmb.gov.*

FOR FURTHER INFORMATION CONTACT: Mary Johnson, General Counsel, National Mediation Board, 202–692–5050, *infoline@nmb.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On August 7, 1992, OGE published the OGE Standards of Ethical Conduct for Employees of the Executive Branch (OGE Standards). See 57 FR 35006–35067, as corrected at 57 FR 48557, 57 FR 52483, and 60 FR 51167, with additional grace period extensions for certain existing provisions at 59 FR 4779–4780, 60 FR 6390–6391, and 60 FR 66857–66858. The OGE Standards, codified at 5 CFR part 2635, effective February 3, 1993, established uniform standards of ethical conduct that apply to all executive branch personnel. Section 2635.105 of the OGE Standards authorizes an agency, with the concurrence of OGE, to adopt agency-specific supplemental regulations that are necessary to properly implement its ethics program. The NMB, with OGE's concurrence, has determined that the following supplemental regulation is necessary to the successful implementation of its ethics program.

II. Analysis of the Interim Regulations

Section 10101.101 General

Section 10101.101 explains that the supplemental regulations apply to all employees of the National Mediation Board and supplement the OGE Standards.

Section 10101.102 Prior Approval for Outside Employment

The OGE Standards, at 5 CFR 2635.803, specifically recognize that individual agencies may find it necessary or desirable to supplement the executive branch-wide regulations with a requirement for their employees to obtain approval before engaging in outside employment or activities. In accordance with 5 CFR 2635.803, the NMB has determined that it is desirable for the purpose of administering its ethics program to require employees to obtain approval before engaging in outside employment, regardless of whether that employment is compensated or uncompensated. This approval requirement will help ensure that potential ethical problems are resolved before employees undertake outside employment that could involve a violation of applicable statutes or the OGE Standards. Section 10101.102(a) provides that NMB employees must obtain prior written approval before engaging in compensated or uncompensated outside employment.

Section 10101.102(b) sets forth procedures for requesting such approval. Section 10101.102(b)(1) states that requests for approval of outside employment be submitted in writing in advance of undertaking the employment. Section 10101.102(b)(2) requires that, within 30 calendar days of a significant change in the nature or the scope of the outside employment or in the employee's official position, the employee shall submit a revised request.

Section 10101.102(c) sets forth the standard to be applied by the Board or its designee in acting on requests for prior approval of outside employment. Under this standard, approval shall be granted unless the Board or its designee determines that the outside employment is expected to involve conduct prohibited by statute or Federal regulation, including 5 CFR part 2635. Section 10101.102(c) further provides that, before granting approval, the Board or its designee shall provide the request to the Designated Agency Ethics Official (DAEO) in order for the employee to receive written ethics guidance and that this written ethics guidance shall be appended to the written approval.

Section 10101.102(d) broadly defines ''employment'' for purposes of this section to cover any form of non-Federal employment or business relationship involving the provision of personal services, including writing when done under an arrangement with another person for production or publication of the written product. The definition of employment does not, however, include participation in the activities of nonprofit charitable, religious, professional, social, fraternal, and similar organizations unless such activities are for compensation other than the reimbursement of expenses, involve the provision of professional services or advice, or the organization's activities are devoted substantially to matters relating to the employee's official duties as defined in 5 CFR 2635.807(a)(2)(i)(B) through (E).

III. Matters of Regulatory Procedure

Under 5 U.S.C. 553(a)(2), rules relating to agency management or personnel are exempt from the notice and comment rulemaking requirements of the Administrative Procedure Act (APA). In addition, under 5 U.S.C. 553(b)(3)(A), notice and comment rulemaking requirements do not apply to rules concerning matters of agency organization, procedure, or practice. Given that the rule concerns matters of agency management or personnel, and organization, procedure, or practice, the notice and comment requirements of the APA do not apply here. Nor is a public hearing required under 45 U.S.C. 160a. Furthermore, under 5 U.S.C. 553(b)(3)(B), the NMB finds that good cause exists to waive the proposed rulemaking requirements under the APA because the notice and comment procedures would be contrary to the public interest. The Federal Aviation Administration Modernization and Reform Act of 2012 included a provision for the Government Accountability Office (GAO) to evaluate NMB programs and activities every 2 years. In its most recent evaluation, GAO recommended that the NMB implement internal controls to ensure that employee requests for outside employment comply with OGE Standards and federal law. For this reason, the NMB finds good cause to issue this regulation as an interim final rule with a provision for a 60 day public comment period. The NMB will review all comments received during the comment period and will consider any modifications that appear appropriate in adopting this rule as final, with the concurrence of OGE.

Executive Order 12866

This rule is not a significant rule for purposes of Executive Order 12866 and has not been reviewed by the Office of Management and Budget.

Regulatory Flexibility Act

As required by the Regulatory Flexibility Act, the NMB certifies that these regulatory changes will not have a significant impact on small business entities. This rule will not have any significant impact on the quality of the human environment under the National Environmental Policy Act.

Paperwork Reduction Act

The NMB has determined that the Paperwork Reduction Act does not apply because this interim regulation does not contain any information collection requirements that require the approval of the Office of Management and Budget.

List of Subjects in 5 CFR Part 10101

Conflicts of interests, Government employees.

Dated: October 18, 2018.

By direction of the Board.

Mary Johnson,

General Counsel, National Mediation Board.

Emory A. Rounds, III,

Director, U.S. Office of Government Ethics.

■ For the reasons set forth in the preamble, the National Mediation Board with the concurrence of the U.S. Office of Government Ethics, is amending title 5 of the Code of Federal Regulations by establishing chapter CI, consisting of part 10101, to read as follows:

CHAPTER CI—NATIONAL MEDIATION BOARD

PART 10101—SUPPLEMENTAL STANDARDS OF ETHICAL CONDUCT FOR EMPLOYEES OF THE NATIONAL MEDIATION BOARD

Sec.

10101.101 General.
10101.102 Prior approval for outside employment.

Authority: 5 U.S.C. 7301; 5 U.S.C. App. (Ethics in Government Act of 1978); 44 Stat. 577, as amended; 45 U.S.C. 151, 160a; E.O. 12674, 54 FR 15159, 3 CFR, 189 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3CFR, 1990 Comp., p. 306; 5 CFR 2635.105, 2635.803.

§ 10101.101 General.

Purpose. In accordance with 5 CFR 2635.105, the regulations in this part apply all employees of the National Mediation Board (NMB) and supplement the Standards of Ethical Conduct for Employees of the Executive Branch at 5 CFR 2635.

§ 10101.102 Prior approval for outside employment.

(a) *General Requirement.* Before engaging in compensated or uncompensated outside employment, all National Mediation Board employees must obtain written approval from the Board or its designee.

(b) *Procedure for requesting approval.* (1) The approval by the Board or its designee shall be requested in writing in advance of engaging in outside employment.

(2) Upon a significant change in the nature of scope of the outside employment or in the employee's official position, the employee shall submit a revised request for approval within 30 calendar days.

(c) *Standard for approval.* (1) Approval shall be granted unless the Board or its designee determines that the outside employment is expected to involve conduct prohibited by statute or Federal regulation, including 5 CFR part 2635.

(2) As part of the approval process, the Board or its designee shall provide the request to the Designated Agency Ethics Official (DAEO) in order for the employee to receive written ethics guidance. In the event, the DAEO is the Board's designee, the DAEO shall provide written ethics guidance upon receiving the request. This written ethics guidance shall be appended to the written approval.

(d) *Definition of employment.* For purposes of this section, ''employment'' means any form of non-Federal employment or business relationship, compensated or uncompensated, involving the provision of personal services by the employee. It includes, but is not limited to personal services as an officer, director, employee, agent, attorney, consultant, contractor, general partner, trustee, teacher, or speaker. It includes writing when done under an arrangement with another person for production or publication of the written product. It does not, however, include participation in the activities of a nonprofit charitable, religious, professional, social, fraternal, educational, recreational, public service or civic organization, unless such activities are for compensation other than reimbursement of expenses; such activities involve the provision of professional services or advice; or the organization's activities are devoted substantially to matters relating to the employee's official duties as defined in 5 CFR 2635.807(a)(2)(i)(B) through (E).

[FR Doc. 2018–23548 Filed 10–31–18; 8:45 am]

BILLING CODE 7550–01–P

FEDERAL LABOR RELATIONS AUTHORITY

5 CFR Chapter XIV

Changes to Current Addresses and Geographic Jurisdictions

AGENCY: Federal Labor Relations Authority.

ACTION: Final rule.

SUMMARY: This document amends regulations listing the current addresses and describing the geographic jurisdictions of the Federal Labor Relations Authority, General Counsel of the Federal Labor Relations Authority, and the Federal Service Impasses Panel. These changes reflect the closing of the Boston Regional Office and changes to the geographical jurisdictions of the

Washington, DC and Chicago Regional Directors.

DATES: Effective November 16, 2018.

FOR FURTHER INFORMATION CONTACT: William Tosick, Executive Director, Federal Labor Relations Authority, 1400 K St. NW, Washington, DC 20424, (202) 218–7791, *wtosick@flra.gov*.

SUPPLEMENTARY INFORMATION: Effective January 28, 1980, the Authority and the General Counsel published, at 45 FR 3482, January 17, 1980, final rules and regulations to govern the processing of cases by the Authority and the General Counsel under chapter 71 of title 5 of the United States Code. These rules and regulations are required by title VII of the Civil Service Reform Act of 1978 and are set forth in 5 CFR chapter XIV (2018).

After an examination of budgets, caseloads, rental costs, operating costs, and staffing, the Authority is closing its Boston Regional Office and reassigning its jurisdiction to the Washington, DC and Chicago Regional Directors, effective November 16, 2018. The Authority expects no adverse effect on the quality or efficiency of casehandling as a result of the Boston Regional Office closure.

This amendment updates paragraphs (d) and (f) of Appendix A to 5 CFR chapter XIV to reflect the new organizational structure by removing the Boston Regional Office from the list of current addresses, telephone numbers, and fax numbers of the Authority's Regional Offices and by revising the geographical jurisdictions of the Federal Labor Relations Authority. As this rule pertains to agency organization, procedure, or practice, it is exempt from prior notice and public comment pursuant to 5 U.S.C. 553(b)(A). For this same reason, pursuant to 5 U.S.C. 553(d)(3), the Authority finds that good cause exists for not providing a more delayed effective date. This type of action is also exempt from review under Executive Orders 12866 (58 FR 51735, October 4, 1993), 13563 (76 FR 3821, January 21, 2011), and 13771 (82 FR 9339, February 3, 2017).

For additional information regarding case handling procedures following the Boston Regional Office closure, please go to *www.flra.gov*.

The opinion of the Authority's majority and the dissenting opinion of Member DuBester with respect to the closure of the Federal Labor Relations Authority's Boston and Dallas Regional Offices are published at Appendix A, 83 FR 46349, 46350–46368, September 13, 2018.

List of Subjects in 5 CFR Chapter XIV

Administrative practice and procedure.

Chapter XIV—Federal Labor Relations Authority

For the reasons set forth in the preamble and under the authority of 5 U.S.C. 7134, the Authority amends 5 CFR chapter XIV as follows:

■ 1. Appendix A to 5 CFR chapter XIV is amended by removing paragraph (d)(1), redesignating paragraphs (d)(2) through (d)(6) as (d)(1) through (d)(5), and revising paragraph (f) to read as follows:

Appendix A to 5 CFR Chapter XIV—Current Addresses and Geographic Jurisdictions

* * * * *

(f) The geographic jurisdictions of the Regional Directors of the Federal Labor Relations Authority are as follows:

State or other locality	Regional office
Alabama	Atlanta.
Alaska	San Francisco.
Arizona	Denver.
Arkansas	Atlanta.
California	San Francisco.
Colorado	Denver.
Connecticut	Washington, DC.
Delaware	Washington, DC.
District of Columbia	Washington, DC.
Florida	Atlanta.
Georgia	Atlanta.
Hawaii and all land and water areas west of the continents of North and South America (except coastal islands) to long. 90 degrees East.	San Francisco.
Idaho	San Francisco.
Illinois	Chicago.
Indiana	Chicago.
Iowa	Chicago.
Kansas	Denver.
Kentucky	Chicago.
Louisiana	Atlanta.
Maine	Washington, DC.
Maryland	Washington, DC.
Massachusetts	Washington, DC.
Michigan	Chicago.
Minnesota	Chicago.
Mississippi	Atlanta.
Missouri	Chicago.
Montana	Denver.
Nebraska	Denver.
Nevada	San Francisco.
New Hampshire	Washington, DC.
New Jersey	Washington, DC.
New Mexico	Denver.
New York	Washington, DC.
North Carolina	Atlanta.
North Dakota	Chicago.
Ohio	Chicago.
Oklahoma	Denver.
Oregon	San Francisco.

State or other locality	Regional office
Pennsylvania	Washington, DC.
Puerto Rico and coastal islands	Chicago.
Rhode Island	Washington, DC.
South Carolina	Atlanta.
South Dakota	Chicago.
Tennessee	Chicago.
Texas	Denver.
Utah	Denver.
Vermont	Washington, DC.
Virginia	Washington, DC.
Washington	San Francisco.
West Virginia	Washington, DC.
Wisconsin	Chicago.
Wyoming	Denver.
Virgin Islands	Atlanta.
Panama/limited FLRA jurisdiction	Atlanta.
All land and water areas east of the continents of North and South America to long. 90 degrees East, except the Virgin Islands, Panama/limited FLRA jurisdiction, Puerto Rico and coastal islands.	Washington, DC.

Authority: 5 U.S.C. 7134.

Dated: October 29, 2018.

For the Federal Labor Relations Authority.

William Tosick,

Executive Director.

[FR Doc. 2018–23897 Filed 10–31–18; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2018–0437; Airspace Docket No. 18–ASO–5]

RIN 2120–AA66

Establishment and Modification of Area Navigation Routes, Florida Metroplex Project; Southeastern United States

Republication

Editorial Note: Rule document 2018–18508 originally published on pages 43750 through 43756, in the issue of Tuesday, August 28, 2018. In that publication, on page 43755, under the heading ''Q–81 TUNSL, FL TO HONID, GA [NEW]'' make the following corrections: (1) In the second line, in the first column, remove ''FIX''; and (2) in the same line, in the second column, ''WP'' should read ''FIX''. The corrected document is published here in its entirety.

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes 16 high altitude area navigation (RNAV) routes (Q-routes), and modifies 7 existing Q-routes, in support of the Florida Metroplex Project. The routes were developed to improve the efficiency of the National Airspace System (NAS) and reduce dependency on ground-based navigational systems that cause system inefficiencies due to their limitations. This action also makes minor corrections to the waypoint names and geographic coordinates of certain Q-routes.

DATES: Effective date 0901 UTC, November 8, 2018. 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 7400.11B, 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 7400.11B at NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

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

FOR FURTHER INFORMATION CONTACT: Paul Gallant, Airspace Policy Group, Office of Airspace Services, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

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 the 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 supports the air traffic service route structure in the southeastern United States to maintain the efficient flow of air traffic.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** for Docket No. FAA–2018–0437 (83 FR 26612; June 8, 2018) to establish 16 high altitude area navigation (RNAV) routes (Q-routes), and modify 7 existing Q-routes in support of the Florida Metroplex Project. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal. One comment was received.

Area navigation routes are published in paragraph 2006, of FAA Order 7400.11B dated August 3, 2017, and effective September 15, 2017, which is incorporated by reference in 14 CFR 71.1. The area navigation routes listed in this document will be subsequently published in the Order.

Discussion of Comment

The commenter did not present an objection to the proposal, but posed questions regarding the benefits of the stated reduction in air traffic control sector complexity; reduced pilot-to-air traffic controller communications; and

details of the expected increases in NAS capacity that were noted in the NPRM.

The implementation of these routes will reduce sector complexity and air traffic controller workload by reducing the need for offset radar vectors when climbing and descending air traffic. The routes will deconflict dedicated route options when transitioning departures and arrivals from the overhead streams. Additionally, the routes will create parallel, de-conflicted routes to achieve higher throughput, more optimal altitudes, and increased routing options, particularly in constricted airspace along the mid-Atlantic U.S. coast. These initiatives are expected to reduce air traffic controller and pilot workload as well as enhance NAS efficiency.

Regarding NAS capacity improvements, the implementation of the routes will contribute to the integration of recent Metroplex work along the East Coast into the high altitude enroute structure. Capacity will be enhanced through more efficient routings, reduced delays, and increased flexibility for users. Further, the routes will eliminate reliance on the ground-based navigation aid (NAVAID) structure and will enable the VOR Minimum Operational Network (VOR MON) Program to achieve its cost reduction objectives associated with the decommissioning of designated NAVAIDs. The FAA monitors a number of NAS performance metrics on a daily basis. Additionally, various forecasts are available, such as the FAA Aerospace Forecast, which projects future aviation activity and demand for FAA services. Based on analysis of these data, adjustments can be made where necessary.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017. FAA Order 7400.11B is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11B lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Differences From the NPRM

Minor editorial corrections are made to the descriptions of a number Q-routes as listed below:

In Q–65: The ''LORN'' WP is corrected to read ''LORNN'' WP.

In Q–77: The latitude coordinate for the WIGVO, GA, WP is changed from ''lat. 32°37′24.00″ N,'' to read ''lat. 32°27′24.00″ N''.

In Q–81: The ''BITN'' WP is corrected to read ''BITNY'' WP.

In Q–89: The following WP is inserted between the PRMUS, FL, and the YANTI, GA, WPs: ''SHRKS, FL WP (lat. 30°37′23.23″ N, long. 81°45′59.13″ W)''.

In Q–93 and Q–97: The ''WOPN'' WP is corrected to read ''WOPNR'' WP.

In Q–109: The spelling of ''LAAN, NC'' in the route title line is corrected to read ''LAANA, NC.'' Additionally, the location for the SESUE WP was incorrectly listed as ''GA''. The correct location is ''SC''.

In Q–409: The location for the SESUE WP was incorrectly listed as ''GA''. The correct location is ''SC''.

The Rule

The FAA is amending Title 14, Code of Federal Regulations (14 CFR) part 71 by establishing 16 new Q-routes, and amend 7 existing Q-routes, in the southeastern United States in support of the Florida Metroplex Project. The new routes are designated Q–75, Q–77, Q–79, Q–81, Q–83, Q–85, Q–87, Q–89, Q–93, Q–97, Q–99, Q–109, Q–113, Q–135, Q–172, and Q–409. In addition, existing routes Q–65, Q–69, Q–103, Q–104, Q–110, Q–116, and Q–118 are amended. The end points of the new and amended routes are listed below. Full route descriptions are in ''The Amendment'' section of this rule. The full route descriptions include the corrections listed in the ''Differences from the NPRM'' section, above.

The new Q-routes are as follows:

Q–75: Q–75 extends between the ENEME, GA, WP (in southeast GA) and the Greensboro, NC, VORTAC.

Q–77: Q–77 extends between the OCTAL, FL, WP (on the southeast FL coast) and the WIGVO, GA, WP (near Union, GA).

Q–79: Q–79 extends between the MCLAW, FL, WP (near the Florida Keys) and the Atlanta, GA, VORTAC. This provides linkage to routes going to the Caribbean area.

Q–81: Q–81 extends between the TUNSL, FL, WP (near the FL Keys) and the HONID, GA, WP (in southwest GA).

Q–83: Q–83 extends between the JEVED, GA, WP (off the southeast GA coast) and the SLOJO, SC, WP (in northern SC).

Q–85: Q–85 extends between the LPERD, FL, WP (off the northeast FL coast) and the SMPRR, NC, WP (in southern NC).

Q–87: Q–87 extends between the PEAKY, FL, WP (near Marathon, FL) and the LCAPE, SC, WP (near the SC—NC line).

Q–89: Q–89 extends between the MANLE, FL, WP (off the central Florida coast) and the Atlanta, GA, VORTAC.

Q–93: Q–93 extends between the MCLAW, FL, WP (near the Florida Keys) and the QUIWE, SC, WP (in southwest SC).

Q–97: Q–97 extends between the TOVAR, FL, WP (along the southeast Florida coast) and the ELLDE, NC, WP (in southern NC).

Q–99: Q–99 extends between the DOFFY, FL, WP (in northern Florida) and the POLYY, NC, WP (near the SC—NC line).

Q–109: Q–109 extends between the DOFFY, FL, WP (in northern Florida) and the LAANA, NC, WP (in southern NC).

Q–113: Q–113 extends between the RAYVO, SC, WP (in east central SC) and the SARKY, SC, WP (near the SC—NC line).

Q–135: Q–135 extends between the JROSS, SC, WP (north of Beaufort, SC) and the RAPZZ, NC, WP (in southern NC).

Q–172: Q–172 extends between the YUTEE, SC, WP (in western SC) and the RAPZZ, NC, WP (in southern NC).

Q–409: Q–409 extends between the ENEME, GA, WP (in southeast GA) and the MRPIT, NC, WP (in southern NC).

The amended Q-routes are as follows:

Q–65: Q–65 currently extends between the JEFOI, GA, WP and the Rosewood, OH, VORTAC. The route is extended to approximately 200 nautical miles (NM) south of the JEFOI, GA, WP to the KPASA, FL, WP. The KPASA, FL; DOFFY, FL; FETAL, FL; and ENEME, GA, WPs are added prior to the JEFOI, GA, WP. The TRASY, GA, WP is added between the JEFOI, GA, and the CESKI, GA, WPs.

Q–69: Q–69 currently extends between the BLAAN, SC, WP and the RICCS, WV, WP. The route is extended approximately 210 NM to the south of the BLAAN, SC, WP to the VIYAP, GA, Fix (located near Brunswick, GA). The extended route segments consist the of VIYAP, GA, fix; OLBEC, GA, WP; ISUZO, GA, WP; and the GURGE, SC, WP. The EMCET, SC, WP is inserted between the BLAAN, SC, WP and the RYCKI, NC, WP.

Q–103: Q–103 currently extends between the Pulaski, VA, VORTAC and the AIRRA, PA, WP. The route is extended to the south of the Pulaski, VA, VORTAC to the CYNTA, GA, WP (in southeastern GA). The extended segments consist of the CYNTA, GA, WP; PUPYY, GA, WP; RIELE, SC, WP; EMCET, SC, WP; and the SLOJO, SC, WP.

Q–104: Q–104 currently extends between the DEFUN, FL, fix, and the Cypress, FL, VOR/DME. The route is amended by removing the DEFUN, FL, fix; and the Cypress, FL, VOR/DME from the route. The ACORI, AL, WP, and the CABLO, GA, WP, are added prior to the HEVVN, FL, fix. The ENDEW, FL, WP is added between the SWABE, FL, fix and the St. Petersburg, FL, VORTAC.

Q–110: Q–110 currently extends between the BLANS, IL, WP, and the THNDR, FL, Fix. The amended route is the same as currently charted between the BLANS, IL, WP and the JYROD, AL, WP. Beyond that point, the route is realigned to terminate at the new OCTAL, FL, WP (on the southeast FL coast). The FEONA, GA; GULFR, FL; BRUTS, FL; KPASA, FL; RVERO, FL; WPs, and the THNDR, FL, fix, are removed. The DAWWN, GA; JOKKY, FL; AMORY, FL; SMELZ, FL; and SHEEK, FL waypoints are inserted between the JYROD, AL, WP and the JAYMC, FL, WP. After JAYMC, the route proceeds to the OCTAL, FL, WP.

Q–116: Q–116 currently extends between the KPASA, FL, WP, and the CEEYA, GA, WP. The current KPASA, FL; BRUTS, FL; GULFR, FL; and CEEYA, GA, waypoints are removed. The route is expanded and realigned to extend between the Vulcan, AL, VORTAC and the OCTAL, FL, WP (on the

southeast FL coast). The following waypoints are added between the Vulcan, AL, VORTAC and the OCTAL, FL, WP: DEEDA, GA; JAWJA, FL; MICES, FL; PATOY, FL; SMELZ, FL; SHEEK, FL; and JAYMC, FL.

Q–118: Q–118 currently extends between the Marion, IN, VOR/DME and the KPASA, FL, WP. The amended route adds the Atlanta, GA, VORTAC between the KAILL, GA, WP and the JOHNN, GA, WP; adds the JAMIZ, FL, WP between the JOHNN, GA, and BRUTS, FL, WPs; and adds the JINOS, FL, WP between the BRUTS, FL, and the KPASA, FL, WPs. Additionally, the route is extended to the south of the KPASA, FL, WP to the PEAKY, FL, WP (near Marathon in the Florida Keys). The SHEEK, FL, WP; CHRRI, FL, fix; FEMID, FL, WP and BRIES, FL, WPs are added between the KPASA, FL WP and the PEAKY, FL WP. Q–118 provides linkage to routes from the Caribbean area.

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. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (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 of establishing 16 high altitude area navigation (RNAV) routes (Q-routes), and modifying 7 existing Q-routes, in support of the Florida Metroplex Project qualifies for categorical exclusion under the National Environmental Policy Act and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F—Environmental Impacts: Policies and Procedures, paragraph 5–6.5i—Establishment of new or revised air traffic control procedures conducted at 3,000 feet or more above ground level (AGL), procedures conducted below 3,000 feet AGL that do not cause traffic to be routinely routed over noise sensitive areas, modifications to currently approved procedures conducted below 3,000 feet AGL that do not significantly increase noise over noise sensitive areas; and increases in minimum altitudes and landing minima. As such, this action is not expected to cause any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, this action has been reviewed for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis, and it is determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

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 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017 and effective September 15, 2017, is amended as follows:

Paragraph 2006 United States Area Navigation Routes.

Q–75 ENEME, GA to Greensboro, NC (GSO) [New]

ENEME, GA	WP	(Lat. 30°42′12.09″ N, long. 082°26′09.31″ W)
TEUFL, GA	WP	(Lat. 31°52′00.46″ N, long. 082°01′04.56″ W)
TEEEM, GA	WP	(Lat. 32°08′41.20″ N, long. 081°54′50.57″ W)
SHRIL, GA	WP	(Lat. 32°54′42.21″ N, long. 081°34′09.78″ W)
FISHO, SC	WP	(Lat. 33°16′46.25″ N, long. 081°24′43.52″ W)
ILBEE, SC	WP	(Lat. 34°18′41.66″ N, long. 081°01′07.88″ W)
SLOJO, SC	WP	(Lat. 34°38′46.31″ N, long. 080°39′25.63″ W)
Greensboro, NC (GSO)	VORTAC	(Lat. 36°02′44.49″ N, long. 079°58′34.95″ W)

Q–77 OCTAL, FL to WIGVO, GA [New]

OCTAL, FL	WP	(Lat. 26°09′01.91″ N, long. 080°06′37.51″ W)
MATLK, FL	WP	(Lat. 27°49′36.54″ N, long. 080°57′04.27″ W)
STYMY, FL	WP	(Lat. 28°01′09.65″ N, long. 081°08′41.27″ W)
WAKKO, FL	WP	(Lat. 28°18′00.69″ N, long. 081°24′53.94″ W)
WASUL, FL	WP	(Lat. 28°41′10.59″ N, long. 081°35′14.53″ W)
MJAMS, FL	WP	(Lat. 28°55′37.59″ N, long. 081°36′33.30″ W)
ETORE, FL	WP	(Lat. 29°41′49.00″ N, long. 081°40′47.75″ W)
SHRKS, FL	WP	(Lat. 30°37′23.23″ N, long. 081°45′59.13″ W)
TEUFL, GA	WP	(Lat. 31°52′00.46″ N, long. 082°01′04.56″ W)
WIGVO, GA	WP	(Lat. 32°27′24.00″ N, long. 082°02′18.00″ W)

Q–79 MCLAW, FL to Atlanta, GA (ATL) [New]

MCLAW, FL	WP	(Lat. 24°33′49.00″ N, long. 081°01′00.00″ W)
VAULT, FL	WP	(Lat. 24°45′54.75″ N, long. 081°00′33.72″ W)
FEMID, FL	WP	(Lat. 26°06′29.59″ N, long. 081°27′23.07″ W)
WULFF, FL	WP	(Lat. 27°04′03.14″ N, long. 081°58′44.99″ W)
MOLIE, FL	WP	(Lat. 28°01′55.53″ N, long. 082°18′25.55″ W)
DOFFY, FL	WP	(Lat. 29°15′22.73″ N, long. 082°31′38.10″ W)
YUESS, GA	WP	(Lat. 31°41′00.00″ N, long. 083°33′31.20″ W)
Atlanta, GA (ATL)	VORTAC	(Lat. 33°37′44.68″ N, long. 084°26′06.23″ W)

Q–81 TUNSL, FL to HONID, GA [New]

TUNSL, FL	WP	(Lat. 24°54′02.43″ N, long. 081°31′02.80″ W)
KARTR, FL	FIX	(Lat. 25°29′45.76″ N, long. 081°30′46.24″ W)
FIPES, OG	WP	(Lat. 25°41′30.15″ N, long. 081°37′13.79″ W)
THMPR, FL	WP	(Lat. 26°46′00.21″ N, long. 082°20′23.99″ W)
LEEHI, FL	WP	(Lat. 27°07′21.91″ N, long. 082°34′54.57″ W)

FARLU, FL	WP	(Lat. 27°45′32.56″ N, long. 082°50′43.77″ W)
ENDEW, FL	WP	(Lat. 28°18′01.73″ N, long. 082°55′56.70″ W)
BITNY, OG	WP	(Lat. 28°46′11.98″ N, long. 083°07′53.01″ W)
NICKI, FL	WP	(Lat. 29°15′20.19″ N, long. 083°20′31.80″ W)
HONID, GA	WP	(Lat. 31°38′50.31″ N, long. 084°23′42.60″ W)

Q–83 JEVED, GA to SLOJO, SC [New]

JEVED, GA	WP	(Lat. 31°15′02.60″ N, long. 081°03′40.14″ W)
ROYCO, GA	WP	(Lat. 31°35′10.38″ N, long. 081°02′22.45″ W)
TAALN, GA	WP	(Lat. 31°59′56.18″ N, long. 081°01′41.91″ W)
KONEY, SC	WP	(Lat. 32°17′01.62″ N, long. 081°01′23.79″ W)
WURFL, SC	WP	(Lat. 32°31′46.59″ N, long. 081°01′08.07″ W)
EFFAY, SC	WP	(Lat. 34°15′30.67″ N, long. 080°30′37.94″ W)
SLOJO, SC	WP	(Lat. 34°38′46.31″ N, long. 080°39′25.63″ W)

Q–85 LPERD, FL to SMPRR, NC [New]

LPERD, FL	WP	(Lat. 30°36′09.18″ N, long. 081°16′52.16″ W)
GIPPL, GA	WP	(Lat. 31°22′53.96″ N, long. 081°09′53.70″ W)
ROYCO, GA	WP	(Lat. 31°35′10.38″ N, long. 081°02′22.45″ W)
IGARY, SC	WP	(Lat. 32°34′41.37″ N, long. 080°22′36.01″ W)
PELIE, SC	WP	(Lat. 33°21′23.88″ N, long. 079°44′43.43″ W)
BUMMA, SC	WP	(Lat. 34°01′58.09″ N, long. 079°11′07.50″ W)
KAATT, NC	WP	(Lat. 34°15′35.43″ N, long. 078°59′42.38″ W)
SMPRR, NC	WP	(Lat. 34°26′28.32″ N, long. 078°50′31.80″ W)

Q–87 PEAKY, FL to LCAPE, SC [New]

PEAKY, FL	WP	(Lat. 24°35′23.72″ N, long. 081°08′53.91″ W)
GOPEY, FL	WP	(Lat. 25°09′32.92″ N, long. 081°05′17.11″ W)
GRIDS, FL	WP	(Lat. 26°24′54.27″ N, long. 080°57′11.40″ W)
TIRCO, FL	WP	(Lat. 27°19′05.75″ N, long. 080°51′16.67″ W)
MATLK, FL	WP	(Lat. 27°49′36.54″ N, long. 080°57′04.27″ W)
ONEWY, FL	WP	(Lat. 28°21′53.66″ N, long. 081°03′21.04″ W)
ZERBO, FL	WP	(Lat. 28°54′56.68″ N, long. 081°17′40.13″ W)
DUCEN, FL	WP	(Lat. 29°16′33.83″ N, long. 081°19′23.24″ W)
FEMON, FL	WP	(Lat. 30°27′31.57″ N, long. 081°23′36.20″ W)
VIYAP, GA	FIX	(Lat. 31°15′08.15″ N, long. 081°26′08.18″ W)
TAALN, GA	WP	(Lat. 31°59′56.18″ N, long. 081°01′41.91″ W)
JROSS, SC	WP	(Lat. 32°42′40.00″ N, long. 080°37′38.00″ W)
RAYVO, SC	WP	(Lat. 33°38′44.12″ N, long. 080°04′00.84″ W)
HINTZ, SC	WP	(Lat. 34°10′11.02″ N, long. 079°44′48.12″ W)
REDFH, SC	WP	(Lat. 34°22′36.35″ N, long. 079°37′08.34″ W)
LCAPE, SC	WP	(Lat. 34°33′03.47″ N, long. 079°30′39.47″ W)

Q–89 MANLE, FL to Atlanta, GA (ATL) [New]

MANLE, FL	WP	(Lat. 28°42′26.16″ N, long. 080°24′23.71″ W)
WAKUP, FL	WP	(Lat. 28°51′47.62″ N, long. 080°40′26.97″ W)
PRMUS, FL	WP	(Lat. 29°49′05.67″ N, long. 081°07′20.74″ W)
SHRKS, FL	WP	(Lat. 30°37′23.23″ N, long. 081°45′59.13″ W)
YANTI, GA	WP	(Lat. 31°47′22.38″ N, long. 082°51′32.65″ W)
Atlanta, GA (ATL)	VORTAC	(Lat. 33°37′44.68″ N, long. 084°26′06.23″ W)

Q–93 MCLAW, FL to QUIWE, SC [New]

MCLAW, FL	WP	(Lat. 24°33′49.00″ N, long. 081°01′00.00″ W)
VAULT, FL	WP	(Lat. 24°45′54.75″ N, long. 081°00′33.72″ W)
LINEY, FL	WP	(Lat. 25°16′44.02″ N, long. 080°53′15.43″ W)
FOBIN, FL	WP	(Lat. 25°47′02.00″ N, long. 080°46′00.89″ W)
EBAYY, FL	WP	(Lat. 27°43′40.20″ N, long. 080°30′03.59″ W)
MALET, FL	FIX	(Lat. 28°41′29.90″ N, long. 080°52′04.30″ W)
DEBRL, FL	WP	(Lat. 29°17′48.73″ N, long. 081°08′02.88″ W)
KENLL, FL	WP	(Lat. 29°34′28.35″ N, long. 081°07′25.26″ W)
PRMUS, FL	WP	(Lat. 29°49′05.67″ N, long. 081°07′20.74″ W)
WOPNR, OA	WP	(Lat. 30°37′36.03″ N, long. 081°04′26.44″ W)
GIPPL, GA	WP	(Lat. 31°22′53.96″ N, long. 081°09′53.70″ W)
ISUZO, GA	WP	(Lat. 31°57′47.85″ N, long. 081°14′14.79″ W)
FISHO, SC	WP	(Lat. 33°16′46.25″ N, long. 081°24′43.52″ W)
QUIWE, SC	WP	(Lat. 33°57′05.56″ N, long. 081°30′07.93″ W)

Q–97 TOVAR, FL to ELLDE, NC [New]

TOVAR, FL	WP	(Lat. 26°33′05.09″ N, long. 080°02′19.75″ W)
EBAYY, FL	WP	(Lat. 27°43′40.20″ N, long. 080°30′03.59″ W)
MALET, FL	FIX	(Lat. 28°41′29.90″ N, long. 080°52′04.30″ W)
DEBRL, FL	WP	(Lat. 29°17′48.73″ N, long. 081°08′02.88″ W)
KENLL, FL	WP	(Lat. 29°34′28.35″ N, long. 081°07′25.26″ W)
PRMUS, FL	WP	(Lat. 29°49′05.67″ N, long. 081°07′20.74″ W)
WOPNR, OA	WP	(Lat. 30°37′36.03″ N, long. 081°04′26.44″ W)
JEVED, GA	WP	(Lat. 31°15′02.60″ N, long. 081°03′40.14″ W)
CAKET, SC	WP	(Lat. 32°31′08.63″ N, long. 080°16′09.21″ W)
ELMSZ, SC	WP	(Lat. 33°40′36.61″ N, long. 079°17′59.56″ W)
YURCK, NC	WP	(Lat. 34°11′14.80″ N, long. 078°52′40.62″ W)
ELLDE, NC	WP	(Lat. 34°24′14.57″ N, long. 078°41′50.60″ W)

Q99 DOFFY, FL to POLYY, NC [New]

DOFFY, FL	WP	(Lat. 29°15′22.73″ N, long. 082°31′38.10″ W)
CAMJO, FL	WP	(Lat. 30°30′32.00″ N, long. 082°41′11.00″ W)
HEPAR, GA	WP	(Lat. 31°05′13.00″ N, long. 082°33′46.00″ W)
TEEEM, GA	WP	(Lat. 32°08′41.20″ N, long. 081°54′50.57″ W)
BLAAN, SC	WP	(Lat. 33°51′09.38″ N, long. 080°53′32.78″ W)

BWAGS, SC	WP	(Lat. 34°00′03.77″ N, long. 080°45′12.26″ W)
EFFAY, SC	WP	(Lat. 34°15′30.67″ N, long. 080°30′37.94″ W)
WNGUD, SC	WP	(Lat. 34°41′53.16″ N, long. 080°06′12.12″ W)
POLYY, NC	WP	(Lat. 34°48′37.54″ N, long. 079°59′55.81″ W)

Q–109 DOFFY, FL to LAANA, NC [New]

DOFFY, FL	WP	(Lat. 29°15′22.73″ N, long. 082°31′38.10″ W)
CAMJO, FL	WP	(Lat. 30°30′32.00″ N, long. 082°41′11.00″ W)
HEPAR, GA	WP	(Lat. 31°05′13.00″ N, long. 082°33′46.00″ W)
TEEEM, GA	WP	(Lat. 32°08′41.20″ N, long. 081°54′50.57″ W)
RIELE, SC	WP	(Lat. 32°37′27.14″ N, long. 081°23′34.97″ W)
PANDY, SC	WP	(Lat. 33°28′29.39″ N, long. 080°26′55.21″ W)
RAYVO, SC	WP	(Lat. 33°38′44.12″ N, long. 080°04′00.84″ W)
SESUE, SC	WP	(Lat. 33°52′02.58″ N, long. 079°33′51.88″ W)
BUMMA, SC	WP	(Lat. 34°01′58.09″ N, long. 079°11′07.50″ W)
YURCK, NC	WP	(Lat. 34°11′14.80″ N, long. 078°52′40.62″ W)
LAAN, NC	WP	(Lat. 34°19′41.35″ N, long. 078°35′37.16″ W)

Q–113 RAYVO, SC to SARKY, SC [New]

RAYVO, SC	WP	(Lat. 33°38′44.12″ N, long. 080°04′00.84″ W)
CEELY, SC	WP	(Lat. 34°12′54.72″ N, long. 079°27′57.01″ W)
SARKY, SC	WP	(Lat. 34°25′41.43″ N, long. 079°14′17.50″ W)

Q–135 JROSS, SC to RAPZZ, NC [New]

JROSS, SC	WP	(Lat. 32°42′40.00″ N, long. 080°37′38.00″ W)
PELIE, SC	WP	(Lat. 33°21′23.88″ N, long. 079°44′43.43″ W)
ELMSZ, SC	WP	(Lat. 33°40′36.61″ N, long. 079°17′59.56″ W)
RAPZZ, NC	WP	(Lat. 34°15′03.34″ N, long. 078°29′17.58″ W)

Q–172 YUTEE, SC to RAPZZ, NC [New]

YUTEE, SC	WP	(Lat. 33°47′28.54″ N, long. 081°33′19.15″ W)
BWAGS, SC	WP	(Lat. 34°00′03.77″ N, long. 080°45′12.26″ W)
HINTZ, SC	WP	(Lat. 34°10′11.02″ N, long. 079°44′48.12″ W)
CEELY, SC	WP	(Lat. 34°12′54.72″ N, long. 079°27′57.01″ W)
OKNEE, SC	WP	(Lat. 34°15′39.92″ N, long. 079°10′40.68″ W)
KAATT, NC	WP	(Lat. 34°15′35.43″ N, long. 078°59′42.38″ W)
RAPZZ, NC	WP	(Lat. 34°15′03.34″ N, long. 078°29′17.58″ W)

Q–409 ENEME, GA to MRPIT, NC [New]

ENEME, GA	WP	(Lat. 30°42′12.09″ N, long. 082°26′09.31″ W)
PUPYY, GA	WP	(Lat. 31°24′35.58″ N, long. 081°49′06.19″ W)
ISUZO, GA	WP	(Lat. 31°57′47.85″ N, long. 081°14′14.79″ W)
KONEY, SC	WP	(Lat. 32°17′01.62″ N, long. 081°01′23.79″ W)
JROSS, SC	WP	(Lat. 32°42′40.00″ N, long. 080°37′38.00″ W)
SESUE, SC	WP	(Lat. 33°52′02.58″ N, long. 079°33′51.88″ W)
OKNEE, SC	WP	(Lat. 34°15′39.92″ N, long. 079°10′40.68″ W)
MRPIT, NC	WP	(Lat. 34°26′05.09″ N, long. 079°01′45.10″ W)

Q–65 KPASA, FL to Rosewood, OH (ROD) [Amended]

KPASA, FL	WP	(Lat. 28°10′34.00″ N, long. 081°54′27.00″ W)
DOFFY, FL	WP	(Lat. 29°15′22.73″ N, long. 082°31′38.10″ W)
FETAL, FL	WP	(Lat. 30°11′03.69″ N, long. 082°30′24.76″ W)
ENEME, GA	WP	(Lat. 30°42′12.09″ N, long. 082°26′09.31″ W)
JEFOI, GA	WP	(Lat. 31°35′37.02″ N, long. 082°31′18.38″ W)
TRASY, GA	WP	(Lat. 31°55′25.92″ N, long. 082°35′50.51″ W)
CESKI, GA	WP	(Lat. 32°16′21.27″ N, long. 082°40′38.96″ W)
DAREE, GA	WP	(Lat. 34°37′35.72″ N, long. 083°51′35.03″ W)
LORNN, TN	WP	(Lat. 35°21′16.33″ N, long. 084°14′19.35″ W)
SOGEE, TN	WP	(Lat. 36°31′50.64″ N, long. 084°11′35.39″ W)
ENGRA, KY	WP	(Lat. 37°29′02.34″ N, long. 084°15′02.15″ W)
OCASE, KY	WP	(Lat. 38°23′59.05″ N, long. 084°11′05.32″ W)
Rosewood, OH (ROD)	VORTAC	(Lat. 40°17′16.08″ N, long. 084°02′35.15″ W)

Q–69 VIYAP, GA to RICCS, WV [Amended]

VIYAP, GA	FIX	(Lat. 31°15′08.15″ N, long. 081°26′08.18″ W)
OLBEC, GA	WP	(Lat. 31°28′32.85″ N, long. 081°26′17.61″ W)
ISUZO, GA	WP	(Lat. 31°57′47.85″ N, long. 081°14′14.79″ W)
GURGE, SC	WP	(Lat. 32°29′02.26″ N, long. 081°12′41.48″ W)
BLAAN, SC	WP	(Lat. 33°51′09.38″ N, long. 080°53′32.78″ W)
EMCET, SC	WP	(Lat. 34°09′41.99″ N, long. 080°50′12.51″ W)
RYCKI, NC	WP	(Lat. 36°24′43.05″ N, long. 080°25′07.50″ W)
LUNDD, VA	WP	(Lat. 36°44′22.38″ N, long. 080°21′07.11″ W)
ILLSA, VA	WP	(Lat. 37°38′55.85″ N, long. 080°13′18.44″ W)
EWESS, WV	WP	(Lat. 38°21′50.31″ N, long. 080°06′52.03″ W)
RICCS, WV	WP	(Lat. 38°55′14.65″ N, long. 080°05′01.68″ W)

Q–103 CYNTA, GA to AIRRA, PA [Amended]

CYNTA, GA	WP	(Lat. 30°36′27.06″ N, long. 082°05′35.45″ W)
PUPYY, GA	WP	(Lat. 31°24′35.58″ N, long. 081°49′06.19″ W)
RIELE, SC	WP	(Lat. 32°37′27.14″ N, long. 081°23′34.97″ W)
EMCET, SC	WP	(Lat. 34°09′41.99″ N, long. 080°50′12.51″ W)
SLOJO, SC	WP	(Lat. 34°38′46.31″ N, long. 080°39′25.63″ W)
Pulaski, VA (PSK)	VORTAC	(Lat. 37°05′15.74″ N, long. 080°42′46.44″ W)
ASBUR, WV	FIX	(Lat. 37°49′24.41″ N, long. 080°27′51.44″ W)
OAKLE, WV	FIX	(Lat. 38°07′13.80″ N, long. 080°21′44.84″ W)
PERRI, WV	FIX	(Lat. 38°17′50.49″ N, long. 080°18′05.11″ W)
PERKS, WV	FIX	(Lat. 38°39′40.84″ N, long. 080°10′29.36″ W)
RICCS, WV	WP	(Lat. 38°55′14.65″ N, long. 080°05′01.68″ W)

EMNEM, WV	WP	(Lat. 39°31′27.12″ N, long. 080°04′28.21″ W)
AIRRA, PA	WP	(Lat. 41°06′16.48″ N, long. 080°03′48.73″ W)

Q–104 ACORI, AL to St Petersburg, FL (PIE) [Amended]

ACORI, AL	WP	(Lat. 31°46′23.36″ N, long. 085°51′29.51″ W)
CABLO, GA	WP	(Lat. 30°46′29.00″ N, long. 084°50′24.00″ W)
HEVVN, FL	FIX	(Lat. 29°49′19.11″ N, long. 083°53′42.89″ W)
LEGGT, FL	FIX	(Lat. 29°13′22.56″ N, long. 083°30′38.60″ W)
PLYER, FL	FIX	(Lat. 28°56′51.36″ N, long. 083°20′08.59″ W)
SWABE, FL	FIX	(Lat. 28°35′16.32″ N, long. 083°06′31.16″ W)
ENDEW, FL	WP	(Lat. 28°18′01.73″ N, long. 082°55′56.70″ W)
St Petersburg, FL (PIE)	VORTAC	(Lat. 27°54′27.95″ N, long. 082°41′03.51″ W)

Q–110 BLANS, IL to OCTAL, FL [Amended]

BLANS, IL	WP	(Lat. 37°28′09.27″ N, long. 088°44′00.68″ W)
BETIE, TN	WP	(Lat. 36°07′29.88″ N, long. 087°54′01.48″ W)
SKIDO, AL	WP	(Lat. 34°31′49.10″ N, long. 086°53′11.16″ W)
BFOLO, AL	WP	(Lat. 34°03′33.98″ N, long. 086°31′30.49″ W)
JYROD, AL	WP	(Lat. 33°10′53.29″ N, long. 085°51′54.85″ W)
DAWWN, GA	WP	(Lat. 31°28′49.96″ N, long. 084°36′46.69″ W)
JOKKY, FL	WP	(Lat. 30°11′31.47″ N, long. 083°38′41.86″ W)
AMORY, FL	WP	(Lat. 29°13′17.02″ N, long. 082°55′42.90″ W)
SMELZ, FL	WP	(Lat. 28°04′59.00″ N, long. 082°06′34.00″ W)
SHEEK, FL	WP	(Lat. 27°35′15.40″ N, long. 081°46′27.82″ W)
JAYMC, FL	WP	(Lat. 26°58′51.00″ N, long. 081°22′08.00″ W)
OCTAL, FL	WP	(Lat. 26°09′01.91″ N, long. 080°06′37.51″ W)

Q–116 Vulcan, AL (VUZ) to OCTAL, FL [Amended]

Vulcan, AL (VUZ)	VORTAC	(Lat. 33°40′12.48″ N, long. 086°53′59.41″ W)
DEEDA, GA	WP	(Lat. 31°34′13.55″ N, long. 085°00′31.10″ W)
JAWJA, FL	WP	(Lat. 30°10′25.55″ N, long. 083°48′58.94″ W)
MICES, FL	WP	(Lat. 29°51′37.65″ N, long. 083°33′18.30″ W)
PATOY, FL	WP	(Lat. 29°03′52.49″ N, long. 082°54′00.09″ W)
SMELZ, FL	WP	(Lat. 28°04′59.00″ N, long. 082°06′34.00″ W)
SHEEK, FL	WP	(Lat. 27°35′15.40″ N, long. 081°46′27.82″ W)
JAYMC, FL	WP	(Lat. 26°58′51.00″ N, long. 081°22′08.00″ W)
OCTAL, FL	WP	(Lat. 26°09′01.91″ N, long. 080°06′37.51″ W)

Q–118 Marion, IN (MZZ) to PEAKY, FL [Amended]

Marion, IN (MZZ)	VOR/DME	(Lat. 40°29′35.99″ N, long. 085°40′45.30″ W)
HEVAN, IN	WP	(Lat. 39°21′08.86″ N, long. 085°07′46.70″ W)
VOSTK, KY	WP	(Lat. 38°28′15.86″ N, long. 084°43′03.58″ W)
HELUB, KY	WP	(Lat. 37°42′54.84″ N, long. 084°44′28.31″ W)
JEDER, KY	WP	(Lat. 37°19′30.54″ N, long. 084°45′14.17″ W)
GLAZR, TN	WP	(Lat. 36°25′20.78″ N, long. 084°46′49.29″ W)
KAILL, GA	WP	(Lat. 34°01′47.21″ N, long. 084°31′24.18″ W)
Atlanta, GA (ATL)	VORTAC	(Lat. 33°37′44.68″ N, long. 084°26′06.23″ W)
JOHNN, GA	FIX	(Lat. 31°31′22.94″ N, long. 083°57′26.55″ W)
JAMIZ, FL	WP	(Lat. 30°13′46.91″ N, long. 083°19′27.78″ W)
BRUTS, FL	WP	(Lat. 29°30′58.00″ N, long. 082°58′57.00″ W)
JINOS, FL	WP	(Lat. 28°27′45.60″ N, long. 082°08′04.60″ W)
KPASA, FL	WP	(Lat. 28°10′34.00″ N, long. 081°54′27.00″ W)
SHEEK, FL	WP	(Lat. 27°35′15.40″ N, long. 081°46′27.82″ W)
CHRRI, FL	FIX	(Lat. 27°03′00.70″ N, long. 081°39′14.81″ W)
FEMID, FL	WP	(Lat. 26°06′29.59″ N, long. 081°27′23.07″ W)
BRIES, FL	WP	(Lat. 25°03′56.03″ N, long. 081°14′38.35″ W)
PEAKY, FL	WP	(Lat. 24°35′23.72″ N, long. 081°08′53.91″ W)

Issued in Washington, DC, on August 20, 2018.

Rodger A. Dean, Jr.,

Manager, Airspace Policy Group.

[FR Doc. R1–2018–18508 Filed 10–31–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA–2017–C–6238]

Listing of Color Additives Exempt From Certification; Synthetic Iron Oxide

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the color additive regulations to provide for the expanded safe use of synthetic iron oxides as color additives to include use in dietary supplement tablets and capsules. This action is in response to a color additive petition (CAP) filed by Colorcon, Inc.

DATES: This rule is effective December 4, 2018. See section X for further information on the filing of objections. Submit either electronic or written objections and requests for a hearing on the final rule by December 3, 2018.

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. Electronic objections must be submitted on or before December 3, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 3, 2018. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic objections in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your

objection will be made public, you are solely responsible for ensuring that your objection 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 objection, that information will be posted on *https://www.regulations.gov.*

• If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection 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 objections submitted to the Dockets Management Staff, FDA will post your objection, 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–C–6238 for ''Listing of Color Additives Exempt from Certification; Synthetic Iron Oxide.'' Received objections, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or with the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections 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 our 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: Molly A. Harry, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740–3835, 240–402–1075.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a document published in the **Federal Register** on November 9, 2017 (82 FR 52037), we announced that we filed a color additive petition (CAP 7C0308) submitted by Colorcon, Inc., 275 Ruth Rd., Harleysville, PA 19438. The petition proposed to amend the color additive regulations in § 73.200 *Synthetic iron oxide* (21 CFR 73.200) by expanding the permitted uses of synthetic iron oxides as a color additive to include use in dietary supplement tablets and capsules, including coatings and printing inks. The petitioner requested that the proposed uses be permitted at a maximum use level of 5 milligrams (mg), calculated as elemental iron, per day for labeled dosages.

II. Background

Synthetic iron oxides and their hydrated forms are currently approved as color additives for use in human foods and drugs: (1) In sausage casings intended for human consumption in an amount not to exceed 0.10 percent by weight of the finished food (§ 73.200); (2) in soft and hard candy, mints, and chewing gum at levels consistent with good manufacturing practice (GMP), except that they may not be used to color foods for which standards of identity have been issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 431) (FD&C Act), unless the use of the added color is authorized by such standards (§ 73.200); and (3) in ingested or topically applied drugs with a limit for ingested drugs of 5 mg, calculated as elemental iron, per day for labeled or prescribed dosages (21 CFR 73.1200). Synthetic iron oxides also are approved for use as color additives in cosmetics generally, including cosmetics applied to the area of the eye, in amounts consistent with GMP (21 CFR 73.2250).

Synthetic iron oxides and their hydrated forms include red iron oxide (synthetic hematite), yellow iron oxide (synthetic geoethite), black iron oxide (synthetic magnetite), and brown iron oxide, which is a blend of various iron oxides. For the subject petition, synthetic iron oxides are intended for coloring dietary supplement tablets and capsules, including coatings for tablets and capsules and printing inks applied to dietary supplement tablets and capsules, such that the total amount of elemental iron in the dietary supplements does not exceed 5 mg per day for labeled dosages.

III. Safety Evaluation

Under section 721(b)(4) of the FD&C Act (21 U.S.C. 379e(b)(4)), a color additive cannot be listed for a particular use unless the data and information available to FDA establish that the color additive is safe for that use. FDA's color additive regulations in 21 CFR 70.3(i) define ''safe'' to mean that there is convincing evidence that establishes with reasonable certainty that no harm will result from the intended use of the color additive.

To establish with reasonable certainty that a color additive intended for use in foods is not harmful under its intended conditions of use, we consider the projected human dietary exposure to the color additive, the additive's toxicological data, and other relevant information (such as published literature) available to us. We compare an individual's estimated exposure, or estimated daily intake (EDI), of the color additive from all sources to an acceptable daily intake level established by toxicological data. The EDI is determined by projections based on the amount of the color additive proposed for use in particular foods and on data regarding the amount consumed from all sources of the color additive. We commonly use the EDI for the 90th percentile consumer of a color additive as a measure of high chronic exposure.

IV. Safety of Petitioned Use of Color Additive

A. Estimated Dietary Exposure

To support the safety of the proposed use of synthetic iron oxides, Colorcon proposed a maximum use level of the color additive in dietary supplements such that the total amount of elemental iron consumed shall not exceed 5 mg per day for labeled dosages. Using 2-day food consumption data from the 2009–2010 National Health and Nutrition Examination Survey (NHANES) food consumption database, Colorcon estimated exposure to elemental iron from the proposed use in dietary supplements. From the NHANES data, Colorcon determined that 2 dietary supplements are consumed in a 24-hour period at the mean, and 4 at the 90th percentile. We note that these values could represent 2 or 4 different dietary supplements, respectively, with each supplement containing up to 5 mg elemental iron. Considering this, FDA has estimated exposure to elemental iron resulting from the petitioned use of synthetic iron oxides in dietary supplements as described below.

Using more recent NHANES data (2011–2014), FDA determined that the U.S. population aged 2 years and older consumes 2 dietary supplements per day at the mean and 5 supplements per day at the 90th percentile (Ref. 1). In estimating exposure, we presumed that: (1) Each dietary supplement could contain up to 5 mg elemental iron for labeled dosages from the use of synthetic iron oxides, resulting in an exposure to elemental iron of 10 milligrams per person per day (mg/p/d) at the mean and 25 mg/p/d at the 90th percentile; (2) all dietary supplements would contain added synthetic iron oxides; and (3) the added synthetic iron oxides would contain a maximum amount (72 percent) of elemental iron; therefore, the use level of 5 mg elemental iron per labeled dosage of dietary supplement would result in a use level of 6.9 mg synthetic iron oxides per labeled dosage of dietary supplement (Ref. 1).

We estimated an upper-bound exposure to synthetic iron oxides from its use as a color additive in dietary supplement tablets and capsules and in coatings applied to dietary supplement tablets and capsules, but excluding its use in printing inks applied on tablets and capsules, to be 13.8 mg/p/d at the mean and 34.5 mg/p/d at the 90th percentile for the U.S. population aged 2 years and older (Ref. 1). The exposure to elemental iron from the petitioned use of synthetic iron oxides is estimated to be 10 mg/p/d at the mean and 25 mg/p/d at the 90th percentile. Regarding exposure to elemental iron resulting from the proposed use of synthetic iron oxides in printing inks applied on tablets and capsules, we estimated that the amount of elemental iron from the use of synthetic iron oxides in inks for use on tablets and capsules is no more than 5.4 micrograms (µg) per tablet or capsule, which corresponds to 10.8 µg elemental iron/p/d at the mean (2 tablets or capsules) and 27 µg elemental iron/p/d at the 90th percentile level (5 tablets or capsules) (Ref. 1). This exposure is negligible compared to that for use of elemental iron as a color additive in tablets and capsules and in coatings applied to dietary supplements.

In the final rule approving the use of synthetic iron oxides for use in candy, mints, and chewing gum (80 FR 14839, March 20, 2015), FDA discussed that elemental iron from synthetic iron oxides is not readily bioavailable and is poorly absorbed by the human gastrointestinal tract (80 FR 14839 at 14840). Approximately 18 percent of iron from conventional foods and dietary supplements is bioavailable and about 1 percent of iron from synthetic iron oxides is bioavailable (Ref. 1). Taking into account the bioavailability of iron from synthetic iron oxides, the exposure to elemental iron from the petitioned use of synthetic iron oxides for the U.S. population aged 2 years and older is estimated to be 0.10 mg/p/d at the mean and 0.25 mg/p/d at the 90th percentile (Ref 1).

We previously estimated the cumulative exposure to bioavailable elemental iron for the U.S. population to be 3.48 mg/p/d at the mean (Ref. 1). Therefore, considering the exposure of 0.10 mg/p/d for elemental iron from the proposed use of synthetic iron oxides, the updated cumulative exposure to bioavailable iron from the current and proposed sources for the U.S. population aged 2 years and older is estimated to be 3.6 mg/p/d at the mean and 7.2 mg/p/d at the pseudo-90th percentile (Ref. 1).

B. Acceptable Intake Level for Iron

In 2001, the Institute of Medicine (IOM) published a report on dietary reference intakes for vitamins and minerals (Ref. 2). In the report, IOM determined dietary reference intakes and upper limits (ULs) for iron of 40 mg/d for children (2–13 years of age) and 45 mg/d for adolescents and adults (14 years and older) (Ref. 2). The IOM considers the UL as the highest daily intake level of a nutrient that poses no risk of adverse effects with chronic consumption of the nutrient (Ref. 2). The UL is determined using a risk assessment model developed specifically for nutrients and may consider intake from such sources as food, water, nutrient supplements, and pharmacological agents (Ref. 2). The dose-response assessment, which concludes with an estimate of the UL, is built upon three toxicological concepts commonly used in assessing the risk of exposures to chemical substances: No-observed-adverse-effect level, lowest-observed-effect level, and an uncertainty factor (Ref. 2).

We considered the UL established by IOM for iron (45 mg/d) relative to the cumulative exposure for bioavailable elemental iron of 7.2 mg/p/d (at the 90th percentile for U.S. population 2 years and older) as the primary basis for assessing the safety of exposure to elemental iron from the proposed use of synthetic iron oxides (Ref. 3). Additionally, we reviewed scientific articles and other relevant studies available to FDA on the safety of iron (Ref. 3). Because the 90th percentile exposure estimate to bioavailable elemental iron from all dietary sources, including the proposed use of synthetic iron oxides to color dietary supplement tablets and capsules, is significantly below the UL determined by IOM, we conclude that there is a reasonable certainty of no harm from the proposed use of synthetic iron oxide as a color additive in dietary supplement tablets and capsules (Ref. 3).

V. Conclusion

FDA reviewed the data and information in the petition and other available relevant material and determined the petitioned use of synthetic iron oxides in dietary supplement tablets and capsules is safe. We further conclude that the color additive will achieve its intended technical effect and is suitable for the petitioned use. Consequently, we are amending the color additive regulations in 21 CFR part 73 as set forth in this document. In addition, based upon the factors listed in 21 CFR 71.20(b), we continue to conclude that certification of synthetic iron oxides is not necessary for the protection of public health.

VI. Public Disclosure

In accordance with § 71.15 (21 CFR 71.15), the petition and the documents that we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 71.15, we will delete from the documents any materials that are not available for public disclosure.

VII. Analysis of Environmental Impact

We previously considered the environmental effects of this rule, as stated in the November 9, 2017, **Federal Register** notification of petition for CAP 7C0308 (82 FR 52037). We stated that we had determined, under 21 CFR 25.32(k), that this action is of a type that does not individually or cumulatively have a significant effect on the human environment such that neither an environmental assessment nor an environmental impact statement is required. We have not received any new information or comments that would affect our previous determination.

VIII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

IX. Section 301(ll) of the Federal Food, Drug, and Cosmetic Act

Our review of this petition was limited to section 721 of the FD&C Act. This final rule is not a statement regarding compliance with other sections of the FD&C Act. For example, section 301(ll) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act (21 U.S.C. 355), a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exemptions in section 301(ll)(1) to (4) of the FD&C Act applies. In our review of this petition, we did not consider whether section 301(ll) of the FD&C Act or any of its exemptions apply to food containing this color additive. Accordingly, this final rule should not be construed to be a statement that a food containing this color additive, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll) of the FD&C Act. Furthermore, this language is included in all color additive final rules that pertain to food and therefore should not be construed to be a statement of the likelihood that section 301(ll) of the FD&C Act applies.

X. Objections

This rule is effective as shown in the **DATES** section, except as to any provisions that may be stayed by the filing of proper objections. If you will be adversely affected by one or more provisions of this regulation, you may file with the Dockets Management Staff (see **ADDRESSES**) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object, and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

Any objections received in response to the regulation may be seen in the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *https://www.regulations.gov.* We will publish notice of the objections that we have received or lack thereof in the **Federal Register**.

XI. References

The following references marked with an asterisk (*) are on display in the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* The reference without an asterisk is not on public display at *https://www.regulations.gov* because it has copyright restriction but is available at the website address. The reference without an asterisk is available for viewing only at the Dockets Management Staff. FDA has verified the website address, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

*1. Memorandum from D. Doell, Chemistry Review Team, Division of Petition Review, Office of Food Additive Safety (OFAS), Center for Food Safety and Applied Nutrition (CFSAN), FDA to M. Harry, Division of Petition Review, OFAS, CFSAN, FDA, September 17, 2018.

2. Institute of Medicine, ''Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc.'' Washington, DC: National Academies Press (U.S.); 2001. *https://www.ncbi.nlm.nih.gov/books/NBK222310/pdf/Bookshelf_NBK222310.pdf.*

*3. Memorandum from T. Thurmond, Toxicology Team, Division of Petition Review, OFAS, CFSAN, FDA to M. Harry, Division of Petition Review, OFAS, CFSAN, FDA, September 17, 2018.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Foods, 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 73 is amended as follows:

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

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

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

■ 2. Section 73.200 is amended by revising paragraph (c)(1) to read as follows:

§ 73.200 Synthetic iron oxide.

* * * * *

(c) * * *

(1) Synthetic iron oxide may be safely used for human food use subject to the following restrictions:

(i) In sausage casings intended for human consumption in an amount not exceeding 0.10 percent by weight of the finished food.

(ii) In soft and hard candy, mints, and chewing gum at levels consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been issued under section 401 of the Federal Food, Drug, and Cosmetic Act, unless the use of the added color is authorized by such standards.

(iii) In dietary supplement tablets and capsules, including coatings and printing inks, such that the total amount of elemental iron per day for labeled dosages does not exceed 5 milligrams.

* * * * *

Dated: October 26, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–23863 Filed 10–31–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. FDA–2018–N–3648]

Medical Devices; Clinical Chemistry and Clinical Toxicology Devices; Classification of the Insulin Therapy Adjustment Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the insulin therapy adjustment device into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the insulin therapy adjustment device's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective November 1, 2018. The classification was applicable on June 12, 2018.

FOR FURTHER INFORMATION CONTACT: Dina Jerebitski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4550, Silver Spring, MD 20993–0002, 301–796–2411, *Dina.Jerebitski@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the insulin therapy adjustment device as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On August 17, 2017, DreaMed Diabetes, Ltd., submitted a request for De Novo classification of the DreaMed Advisor Pro. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify 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 that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on June 12, 2018, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 862.1358. We have named the generic type of device insulin therapy adjustment device, and it is identified as a device intended to incorporate biological inputs, including glucose measurement data from a continuous glucose monitor, to recommend insulin therapy adjustments as an aid in optimizing insulin therapy regimens for patients with diabetes mellitus.

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—INSULIN THERAPY ADJUSTMENT DEVICE RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Erroneous or extreme changes in insulin dosing recommendations may cause hypoglycemia or hyperglycemia.	Special controls (1) (21 CFR 862.1358(b)(1)), (2) (21 CFR 862.1358(b)(2)), and (3) (21 CFR 862.1358(b)(3)).
Incorrect interpretation of results may lead to inappropriate clinical decision making ...	Special controls (1) (21 CFR 862.1358(b)(1)) and (3) (21 CFR 862.1358(b)(3)).
Incorrect understanding of appropriate device use may lead to inappropriate treatment decisions.	Special controls (1) (21 CFR 862.1358(b)(1)), (2) (21 CFR 862.1358(b)(2)), and (3) (21 CFR 862.1358(b)(3)).
Patient harm due to insecure transmission of data	Special control (1) (21 CFR 862.1358(b)(1)).
Data corruption may lead to inappropriate treatment recommendations	Special control (1) (21 CFR 862.1358(b)(1)).

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. In order for a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. 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.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. 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 the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulations, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR parts 801 and 809, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 862

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 862 is amended as follows:

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

■ 1. The authority citation for part 862 continues to read as follows:

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

■ 2. Add § 862.1358 to subpart B to read as follows:

§ 862.1358 Insulin therapy adjustment device.

(a) *Identification.* An insulin therapy adjustment device is a device intended to incorporate biological inputs, including glucose measurement data from a continuous glucose monitor, to recommend insulin therapy adjustments as an aid in optimizing insulin therapy regimens for patients with diabetes mellitus.

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

(1) Design verification and validation must include the following:

(i) A complete description of the required data inputs, including timeframe over which data inputs must be collected and number of data points required for accurate recommendations;

(ii) A complete description of the types of device outputs and insulin therapy adjustment recommendations, including how the recommendations are generated;

(iii) Robust data demonstrating the clinical validity of the device outputs and insulin therapy recommendations;

(iv) A robust assessment of all input data specifications, including accuracy requirements for continuous glucose monitors and other devices generating data inputs, to ensure accurate and reliable therapy adjustment recommendations. This assessment must include adequate clinical justification for each specification;

(v) A detailed strategy to ensure secure and reliable means of data transmission to and from the device, including data integrity checks, accuracy checks, reliability checks, and security measures;

(vi) Robust data demonstrating that users can understand and appropriately interpret recommendations generated by the device; and

(vii) An appropriate mitigation strategy to minimize the occurrence of dosing recommendation errors, and to mitigate the risk to patients of any residual dosing recommendation errors to a clinically acceptable level.

(2) The device must not be intended for use in implementing automated insulin dosing.

(3) Your 21 CFR 809.10(b) labeling must include:

(i) The identification of specific insulin formulations that have been demonstrated to be compatible with use of the device;

(ii) A detailed description of the specifications of compatible devices that provide acceptable input data (*e.g.,* continuous glucose monitors, insulin pumps) used to provide accurate and reliable therapy adjustment recommendations;

(iii) A detailed description of all types of required data (inputs) and dosing recommendations (outputs) that are provided by the device; and

(iv) A description of device limitations, and instructions to prevent possible disruption of accurate therapy adjustment recommendations (*e.g.,* time zone changes due to travel).

Dated: October 29, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–23912 Filed 10–31–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. FDA–2018–N–3694]

Medical Devices; Clinical Chemistry and Clinical Toxicology Devices; Classification of the Meprobamate Test System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the meprobamate test system into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the meprobamate test system's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective November 1, 2018. The classification was applicable on April 20, 2018.

FOR FURTHER INFORMATION CONTACT: Ryan Lubert, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4545, Silver Spring, MD 20993–0002, 240–402–6357, *Ryan.Lubert@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the meprobamate test system as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA shall classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On February 21, 2017, Lin-Zhi International, Inc. submitted a request for De Novo classification of the LZI Carisoprodol Metabolite (Meprobamate) Enzyme Immunoassay. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify 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 that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on April 20, 2018, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 862.3590. We have named the generic type of device meprobamate test system, and it is identified as a device intended to measure meprobamate in human specimens. Measurements obtained by this device are used to detect the presence of meprobamate to diagnose the use or overdose of meprobamate or structurally-related drug compounds (*e.g.,* prodrugs).

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—MEPROBAMATE TEST SYSTEM RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Clinical action based on incorrect test results (false positive results, false negative results) may lead to inappropriate clinical decision making.	Special controls (1) (21 CFR 862.3590(b)(1)), (2) (21 CFR 862.3590(b)(2)), and (3) (21 CFR 862.3590(b)(3)).
Incorrect understanding of the device and test system and results may lead to inappropriate clinical decision making.	Special controls (2) (21 CFR 862.3590(b)(2)) and (3) (21 CFR 862.3590(b)(3)).

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

At the time of classification, meprobamate test systems are for prescription use only.

III. 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.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. 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 the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulations, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR parts 801 and 809, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 862

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 862 is amended as follows:

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

■ 1. The authority citation for part 862 continues to read as follows:

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

■ 2. Add § 862.3590 to subpart D to read as follows:

§ 862.3590 Meprobamate test system.

(a) *Identification.* A meprobamate test system is a device intended to measure meprobamate in human specimens. Measurements obtained by this device are used to detect the presence of meprobamate to diagnose the use or overdose of meprobamate or structurally-related drug compounds (*e.g.,* prodrugs).

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

(1) Design verification and validation must include:

(i) Robust data demonstrating the accuracy of the device when used in the intended specimen matrix. The accuracy data must include a comparison between the meprobamate test system results and meprobamate results that are measured on an FDA-accepted measurement method that is specific and accurate (*e.g.,* gas or liquid chromatography combined with tandem mass spectrometry).

(ii) Robust analytical data demonstrating the performance characteristics of the device, including, but not limited to, specificity, cross-reactivity to relevant endogenous and exogenous substances, and the reproducibility of analyte detection around the cutoff(s).

(2) The intended use of the device must not include an indication for use in monitoring therapeutic drug concentrations or informing dosing adjustment decisions.

(3) Your 21 CFR 809.10 labeling must include the following:

(i) If indicated for use as a screening test to identify preliminary results for further confirmation, the intended use must state ''This assay provides only a preliminary analytical result. A more specific alternative chemical confirmatory method (*e.g.,* gas or liquid chromatography and mass spectrometry) must be used to obtain a confirmed analytical result. Clinical consideration and professional judgment must be exercised with any drug of abuse test, particularly when the preliminary test result is positive.''

(ii) A limiting statement that reads as follows: ''This test should not be used to monitor therapeutic drug concentrations or to inform dosing adjustment decisions.''

Dated: October 29, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–23911 Filed 10–31–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 625

[Docket No. FHWA–2017–0001]

RIN 2125–AF72

Design Standards for Highways

AGENCY: Federal Highway Administration (FHWA), U.S. Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This final rule updates the regulations governing design standards

and standard specifications that apply to new construction, reconstruction, resurfacing (except for maintenance resurfacing), restoration, and rehabilitation projects on the National Highway System (NHS). In issuing this final rule, FHWA incorporates by reference the latest versions of design standards and standard specifications previously adopted and incorporated by reference, and removes the corresponding outdated or superseded versions of these standards and specifications. Use of the updated standards is required for all NHS projects authorized to proceed with design activities on or after the effective date of the final rule.

DATES: This final rule is effective December 3, 2018. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of December 3, 2018. The incorporation by reference of certain other publications listed in the rule was approved by the Director of the Federal Register as of November 12, 2015.

FOR FURTHER INFORMATION CONTACT: Elizabeth Hilton, Office of Program Administration (HIPA–20), (512) 536–5970, or via email at *Elizabeth.Hilton@dot.gov,* or Jomar Maldonado, Office of the Chief Counsel (HCC–30), (202) 366–1373, or via email at *Jomar.Maldonado@dot.gov*. Office hours are from 8:00 a.m. to 4:30 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

This document, the notice of proposed rulemaking (NPRM), and all comments received may be viewed online under the docket number noted above through the Federal eRulemaking portal at: *http://www.regulations.gov*. Electronic submission and retrieval help and guidelines are available on the website. Please follow the online instructions. An electronic copy of this document may also be downloaded from the Office of the Federal Register's website at: *http://www.archives.gov/federal-register* and the Government Publishing Office's website at: *http://www.gpo.gov/fdsys*.

Background

This rulemaking updates existing regulations governing new construction, reconstruction, resurfacing (except for maintenance resurfacing), restoration, and rehabilitation projects on the NHS (including the Interstate System), by incorporating by reference the current versions of design standards and standard specifications previously adopted and incorporated by reference under 23 CFR 625.4, and removing the outdated or superseded versions of these standards and specifications. Several of these design standards and standard specifications were established by the American Association of State Highway and Transportation Officials (AASHTO) and the American Welding Society (AWS) and were previously adopted by FHWA through rulemaking. The new standards or specifications replace previous versions of these documents and represent the most recent refinements that professional organizations have formally accepted. The FHWA formally adopts them for NHS projects.

The revisions include referencing the 2016 edition of the AASHTO *A Policy on Design Standards—Interstate System*; the 2017 edition of *Transportation Materials, parts 1–3*; the 2017 edition of the *AASHTO Load and Resistance Factor Design (LRFD) Bridge Construction Specifications*; the 2015 edition of the *AASHTO/AWS D1.5M/D1.5:2015 Bridge Welding Code* (as reprinted in 2016), with 2018 Interim Revisions; and the 2017 edition of the *AASHTO LRFD Bridge Design Specifications*. The revisions will also adopt two alternative specifications: the 2013 edition of AASHTO's *Standard Specifications for Structural Supports of Highway Signs, Luminaires, and Traffic Signals* (including Errata September 2013), with 2015 Interim Revisions, as well as the 2015 edition of AASHTO's *LRFD Specifications for Structural Supports for Highway Signs, Luminaires, and Traffic Signals,* with 2017 and 2018 Interim Revisions.

The AASHTO is an organization that represents 52 State highway and transportation agencies (including the District of Columbia and Puerto Rico). Its members consist of the duly constituted heads and other chief officials of those agencies. The Secretary of Transportation is an ex-officio member, and DOT staff participates in various AASHTO activities as nonvoting representatives. Among other functions, AASHTO develops and issues standards, specifications, policies, guides, and related materials for use by the States for highway projects. Many of the standards, policies, and standard specifications that were approved by FHWA and incorporated into 23 CFR part 625 were developed and issued by AASHTO.

While these adopted standards and specifications apply to all projects on the NHS (including the Interstate System), FHWA encourages the use of flexibility and a context-sensitive approach to consider a full range of project and user needs and the impacts to the community and natural and human environment. The FHWA also encourages State departments of transportation (State DOT) and local agencies to consider using design exceptions to achieve a design that balances project and user needs, performance, cost, environmental implications, and community values. These adopted design standards provide a range of acceptable values for highway features, and this flexibility should allow for a design that best suits the desires of the community while satisfying the purpose for the project and needs of its users.

At a minimum, State DOTs and local agencies should select design values based on an evaluation of the context of the facility, needs of all the various project users, safety, mobility (*i.e.,* traffic performance), human and natural environmental impacts, and project costs. For most situations, there is sufficient flexibility within the range of acceptable values to achieve a balanced design. However, when this is not possible, a design exception may be appropriate. State and local agencies may consider designs that deviate from the design standards when warranted based on the conditions, context, and consequences of the proposed projects. Additional information on FHWA's adopted design standards and design exceptions is available at: *http://www.fhwa.dot.gov/design/standards* and in FHWA's publication titled *Mitigation Strategies for Design Exceptions,* available at: *http://safety.fhwa.dot.gov/geometric/pubs/mitigationstrategies/fhwa_sa_07011.pdf*.

Discussion Under 1 CFR Part 51

The documents that FHWA is incorporating by reference are reasonably available to interested parties, primarily State DOTs and local agencies carrying out Federal-aid highway projects. These documents represent the most recent refinements that professional organizations have formally accepted and are currently in use by the transportation industry. The documents are also available for review at DOT's National Transportation Library or may be obtained from AASHTO or AWS. The specific standards are discussed in greater detail elsewhere in this preamble.

Section-by-Section Discussion of Changes to 23 CFR Part 625

The FHWA is removing the introductory text of § 625.4. It is duplicative of information contained in paragraph (d) and does not meet Office of the Federal Register formatting

requirements for incorporation by reference.

The FHWA is revising § 625.4(a)(2) to replace the reference to the January 2005 edition of *A Policy on Design Standards—Interstate System* with the May 2016 edition. This Policy is a comprehensive manual to assist State DOTs and local agencies in administrative, planning, and educational efforts pertaining to design formulation for projects on the Dwight D. Eisenhower National System of Interstate and Defense Highways (Interstate). The AASHTO May 2016 edition incorporates the latest research and current industry practices, and is applicable to new construction and reconstruction projects on the Interstate except in Alaska and Puerto Rico (23 U.S.C. 103(c)(1)(B)(ii)). Resurfacing, restoration, and rehabilitation projects must meet the Interstate standards that were in place at the time of original construction or inclusion into the Interstate System. The updated guide clarifies ambiguities in the prior edition and provides additional flexibility regarding the design traffic volumes to be accommodated. It increases the median width in rural areas to reduce cross-median crashes and adds recommendations about extended access control and multimodal considerations at interchanges. Basic criteria for other geometric design standards remain essentially the same. The Agency considers the changes made in the 2016 version minor in nature.

With respect to the design standards and standards specifications for bridges and structures under § 625.4(b), FHWA is adopting the current versions of the standards and specifications it has previously adopted from AASHTO and AWS. The updated documents contain changes that represent discoveries or improvements in the state-of-the-knowledge and practices of State DOTs and local agencies that have occurred since the previous standards and specifications were incorporated by reference into 23 CFR part 625.

The FHWA is revising § 625.4(b)(2) to incorporate by reference the current version of the revised AASHTO bridge construction specifications entitled *LRFD Bridge Construction Specifications,* 4th Edition. These specifications, which are intended for use in the construction of bridges, employ the LRFD methodology and are designed to be used in conjunction with the below referenced *AASHTO LRFD Bridge Design Specifications.* Changes in the 4th Edition reflect the latest research and developments, and specifications promulgated by AASHTO.

The FHWA is revising § 625.4(b)(3) to incorporate by reference the current version of the revised AASHTO bridge design specifications entitled *AASHTO LRFD Bridge Design Specifications,* 8th Edition. The *AASHTO LRFD Bridge Design Specifications* are intended for use in the design, evaluation, and rehabilitation of bridges, and are mandated by the FHWA for use on all bridges using Federal funding. These Specifications employ the LRFD methodology using factors developing from current statistical knowledge of loads and structural performance. Changes in the 8th Edition reflect the latest research, developments, and specifications promulgated by AASHTO.

The FHWA is making a minor editorial correction to the reference to the *LRFD Movable Highway Bridge Design Specifications* referenced in paragraph § 625.4(b)(4) to change ''including'' to ''with'' when citing the Interim Revisions, but is not changing the material that is already incorporated.

The FHWA is revising § 625.4(b)(5) to incorporate by reference the current version of the revised AASHTO bridge welding code entitled *AASHTO/AWS D1.5M/D1.5:2015–AMD1 Bridge Welding Code;* AASHTO, as corrected and reprinted in 2016, and including 2018 Interim Revisions (The 2015 publication was the 7th edition). This document covers AASHTO welding requirements for welded highway bridges made from carbon and low-alloy construction steels. Chapters cover design of welded connections, workmanship, technique, procedure and performance qualification, inspection, and stud welding. Changes in the 7th Edition, including the 2018 Interim Revisions, reflect the latest research, developments, and specifications promulgated by AASHTO and AWS.

The FHWA is revising § 625.4(b)(7) to incorporate by reference two alternative Specifications applicable to the structural design of supports for highway signs, luminaires, and traffic signals. State DOTs must choose one of these alternative Specifications to guide the design, fabrication, and erection of these types of supports. The first alternative is the most current version of the revised AASHTO structural support specification entitled *Standard Specifications for Structural Supports for Highway Signs, Luminaires, and Traffic Signals,* 6th Edition, AASHTO, 2013, with 2015 Interim Revisions. Changes in the 2015 Interim Revisions reflect more recent research, developments, and specifications promulgated by AASHTO than the prior adopted version. The second alternative Specification is AASHTO's *LRFD Specifications for Structural Supports for Highway Signs, Luminaires, and Traffic Signals,* 1st Edition, AASHTO, 2015, with 2017 and 2018 Interim Revisions. While the LRFD specification is a more comprehensive, improved specification that reflects the latest research and knowledge, the agency has determined that design pursuant to either Specification provides for safe and reliable structural supports for highways signs, luminaires, and traffic signals.

The FHWA is revising § 625.4(c)(2) to incorporate by reference the current version of the revised AASHTO sampling and testing specification entitled 2017 Edition of *Transportation Materials* AASHTO, 2017. It contains specifications, test methods, and provisional standards commonly used in the construction of highway facilities. This edition of the standard specifications will replace those adopted by AASHTO in 1995. Changes in the 2016 standard specifications reflect current materials and testing technologies and practices.

The FHWA is revising § 625.4(c)(3) to update the title and cross-reference of the referenced regulation to ''Quality Assurance Procedures for Construction.''

Use of the updated standards will be required for all NHS projects authorized to proceed with design activities on or after the effective date of the final rule, subject to the exceptions in 23 CFR 625.3(f).

Summary Discussion of Comments Received in Response to the NPRM

On May 11, 2018, FHWA published an NPRM in the **Federal Register** at 83 FR 21972 soliciting public comments on its proposal to update the existing regulations. The following presents an overview of the comments received to the NPRM. The docket contained 4 total comments. The FHWA appreciates the feedback the commenters provided, carefully reviewed and analyzed all the comments that were submitted, and made revisions to the NPRM to incorporate suggestions where necessary.

An individual commented that the *Standard Specifications for Structural Supports for Highway Signs, Luminaires, and Traffic Signals,* 6th Edition, AASHTO, 2013 with 2015 Interim Revisions had been superseded by the *LRFD Specifications for Structural Supports for Highway Signs, Luminaires, and Traffic Signals,* 1st Edition, AASHTO, 2015, with 2017 and 2018 Interim Revisions.

The *LRFD Specification* does not supersede the *Standard Specification*. At this time, many State DOTs are using the Standard Specification and are not ready to fully implement the *LRFD Specification*. Because the LRFD specification is a more comprehensive, improved specification that reflects the latest research and knowledge, FHWA plans to work with AASHTO to develop a timeline to phase out use of the *Standard Specification* in the future. However, the agency has determined that design pursuant to either Specification provides for safe and reliable structural supports for highways signs, luminaires, and traffic signals.[1] Therefore, in the interim, FHWA is adopting the updated *Standard Specification* and the *LRFD Specification as* alternative Specifications applicable to the structural design of supports for highway signs, luminaires, and traffic signals. States DOTs must choose one of these alternative Specifications to guide the design, fabrication, and erection of these types of supports. Accordingly, FHWA has revised § 625.4(b)(7) to accommodate State DOTs that are ready to begin transitioning to the *LRFD Specification*.

That individual also commented that 2018 Interim Revisions had been released for the *2015 Bridge Welding Code,* 7th Edition.

These Interim Revisions were not available when the NPRM was developed, however, FHWA has decided to incorporate the 2018 Interim Revisions by reference in this final rule because they reflect the latest research, developments, and specifications promulgated by AASHTO and AWS.

An individual commenter suggested that rather than adopt specific editions of standards, FHWA should adopt ''the most current version at the time of contract advertisement,'' to eliminate the need to continuously revise 23 CFR part 625.

Procedures and requirements for incorporation by reference are covered in 1 CFR part 51, which requires that the language incorporating a publication by reference be precise and complete and must clearly state the title, date, edition, author, publisher and identification number of the publication. Therefore, no change was made to the final rule.

An individual commented that the updated standards would not allow certain products and therefore provided for a lower margin of safety.

The final rule adopts current versions of industry publications and does not pertain to specific merchandise or products. Use of these current publications will improve safety because the newer versions incorporate updated research within each specific area of concern. Therefore, no change was made to the final rule.

An individual commented that existing practice of allowing for design exceptions undermined existing regulations.

Design exceptions, which have been allowed by the regulations for decades, are essential to developing projects that are congruent with the natural surroundings, community context, and the purpose and need of the project. Therefore, no change was made to the final rule.

Rulemaking Analyses and Notices

Executive Order 12866 (Regulatory Planning and Review), Executive Order 13563 (Improving Regulation and Regulatory Review), Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs), and USDOT Regulatory Policies and Procedures

The FHWA has determined that this action does not constitute a significant regulatory action within the meaning of Executive Order (E.O.) 12866 or within the meaning of DOT regulatory policies and procedures. The amendments update several industry design standards and standard specifications adopted and incorporated by reference under 23 CFR part 625 and removes the corresponding outdated or superseded versions of these standards and specifications. In addition, this action complies with the principles of E.O. 13563. After evaluating the costs and benefits of these amendments, FHWA anticipates that the economic impact of this rulemaking is minimal. These incremental changes are not anticipated to adversely affect, in any material way, any sector of the economy. In addition, these changes will not create a serious inconsistency with any other agency's action or materially alter the budgetary impact of any entitlements, grants, user fees, or loan programs. These updated standards and specifications represent the most recent refinements that professional organizations have formally accepted. The FHWA anticipates that the economic impact of this rulemaking will be minimal; therefore, a full regulatory evaluation is not necessary. Finally, this rule is not an E.O. 13771 regulatory action because it is not significant under E.O. 12866.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (Pub. L. 96–354; 5 U.S.C. 60l–612), FHWA has evaluated the effects of this final rule on small entities, such as local governments and businesses. Based on the evaluation, FHWA anticipates that this action does not have a significant economic impact on a substantial number of small entities. The amendments update several industry design standards and standard specifications adopted and incorporated by reference under 23 CFR part 625. The FHWA believes the projected impact upon small entities that utilize Federal-aid highway program funding for the development of highway improvement projects on the NHS is negligible. Therefore, I certify that the action will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

The FHWA has determined that this rule does not impose unfunded mandates as defined by the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, March 22, 1995, 109 Stat. 48). The actions in this final rule will not result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $155 million or more in any 1 year (when adjusted for inflation) in 2014 dollars for either State, local, and Tribal governments in the aggregate, or by the private sector. In addition, the definition of ''Federal Mandate'' in the Unfunded Mandates Reform Act excludes financial assistance of the type in which State, local, or Tribal governments have authority to adjust their participation in the program in accordance with changes made in the program by the Federal Government. The Federal-aid highway program permits this type of flexibility.

Executive Order 13132 (Federalism Assessment)

The FHWA has analyzed this final rule in accordance with the principles and criteria contained in E.O. 13132. The FHWA has determined that this action does not have sufficient federalism implications to warrant the preparation of a federalism assessment. The FHWA has also determined that this action does not preempt any State law or State regulation or affect the

[1] This determination is supported by National Cooperative Highway Research Program Report 796: *Development and Calibration of AASHTO LRFD Specifications for Structural Supports for Highway Signs, Luminaires, and Traffic Signals,* which found that ''[t]he [LRFD Specifications] were calibrated using the AASHTO [Standard Specifications] allowable stress design method as a baseline,'' which means that both the Standard Specifications and the LRFD Specifications ensure a consistent level of safety.

States' ability to discharge traditional State governmental functions.

Executive Order 12372 (Intergovernmental Review)

The regulations implementing E.O. 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program. This E.O. applies because State and local governments are directly affected by this regulation, which is a condition on Federal highway funding. Local entities should refer to the Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction, for further information.

Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501, *et seq.*), Federal agencies must obtain approval from the Office of Management and Budget for each collection of information they conduct, sponsor, or require through regulations. The FHWA has determined that this final rule does not contain collection of information requirements for the purposes of the PRA.

National Environmental Policy Act

The FHWA has analyzed this final rule for the purposes of the National Environmental Policy Act (NEPA) (42 U.S.C. 4321, *et seq.*) and has determined that this action does not have any effect on the quality of the human and natural environment because it only makes technical changes and incorporate by reference the latest versions of design standards and standard specifications previously adopted and incorporated by reference under 23 CFR part 625 and removes the corresponding outdated or superseded versions of these standards and specifications. The final rule qualifies as a categorical exclusion to NEPA under 23 CFR 771.117(c)(20).

Executive Order 13175 (Tribal Consultation)

The FHWA has analyzed this final rule under EO13175, and believes that it will not have substantial direct effects on one or more Indian Tribes, does not impose substantial direct compliance costs on Indian Tribal governments, and does not preempt Tribal law. This rule does not impose any direct compliance requirements on Indian Tribal governments nor does it have any economic or other impacts on the viability of Indian Tribes. Therefore, a Tribal summary impact statement is not required.

Executive Order 13211 (Energy Effects)

The FHWA has analyzed this final rule under E.O. 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use. The FHWA has determined that this action is not a significant energy action under the E.O. and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required.

Executive Order 12630 (Taking of Private Property)

The FHWA has analyzed this rule under E.O. 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights. The FHWA does not anticipate that this action will effect a taking of private property or otherwise have taking implications under E.O. 12630.

Executive Order 12988 (Civil Justice Reform)

This action meets applicable standards in sections 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Executive Order 13045 (Protection of Children)

The FHWA has analyzed this action under E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks. The FHWA certifies that this action will not cause an environmental risk to health or safety that may disproportionately affect children.

Regulation Identifier Number

A Regulation Identifier Number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN number contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

List of Subjects in 23 CFR Part 625

Design standards, Grant programs—transportation, Highways and roads, Incorporation by reference.

Issued on: October 24, 2018.

Brandye L. Hendrickson,

Deputy Administrator, Federal Highway Administration.

In consideration of the foregoing, FHWA amends 23 CFR part 625 as follows:

PART 625—DESIGN STANDARDS FOR HIGHWAYS

■ 1. The authority citation for part 625 continues to read as follows:

Authority: 23 U.S.C. 109, 315, and 402; Sec. 1073 of Pub. L. 102–240, 105 Stat. 1914, 2012; 49 CFR 1.48(b) and (n).

■ 2. Amend § 625.4 by:
■ a. Removing the introductory text;
■ b. Revising paragraphs (a)(2), (b)(2) through (5), (7), (c)(2) and (3), the introductory text of paragraph (d), and paragraphs (d)(1)(ii), (iv), (v), (vii), and (viii);
■ c. Adding paragraphs (d)(1)(ix) and (x); and
■ d. Revising the introductory text of paragraph (d)(2).

The revisions and additions read as follows:

§ 625.4 Standards, policies, and standard specifications.

(a) * * *

(2) A Policy on Design Standards—Interstate System, AASHTO (paragraph (d) of this section).

* * * * *

(b) * * *

(2) AASHTO LRFD Bridge Construction Specifications (paragraph (d) of this section).

(3) AASHTO LRFD Bridge Design Specifications (paragraph (d) of this section).

(4) AASHTO LRFD Movable Highway Bridge Design Specifications (paragraph (d) of this section).

(5) AASHTO/AWS D1.5M/D1.5 Bridge Welding Code (paragraph (d) of this section).

* * * * *

(7) Standard Specifications for Structural Supports for Highway Signs, Luminaires, and Traffic Signals, (paragraph (d) of this section); or LRFD Specifications for Structural Supports for Highway Signs, Luminaires, and Traffic Signals (paragraph (d) of this section).

* * * * *

(c) * * *

(2) Transportation Materials, AASHTO (paragraph (d) of this section).

(3) Quality Assurance Procedures for Construction, refer to 23 CFR part 637, subpart B.

(d) *Documents incorporated by reference.* The standards required in this section are incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at U.S. Department of Transportation's National Transportation Library at 1200 New

Jersey Avenue SE, Washington, DC 20590; (800) 853–1351 and is available from the sources indicated below. It 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 *www.archives.gov/federal-register/cfr/ibr-locations.html*.

(1) * * *

(ii) A Policy on Design Standards—Interstate System, May 2016.

* * * * *

(iv) AASHTO–LRFD Bridge Construction Specifications, 4th Edition, copyright 2017.

(v) AASHTO LRFD–8, LRFD Bridge Design Specifications, 8th Edition, 2017.

* * * * *

(vii) AASHTO/AWS D1.5M/D1.5: 2015–AMD1, Bridge Welding Code, Amendment: Second Printing December 12, 2016; with

(A) AASHTO BWC–7–I1–OL, 2018 Interim Revisions to AASHTO/AWS D1.5M/D1.5: 2015 Bridge Welding Code, 7th Edition, copyright 2017.

(B) [Reserved]

(viii) AASHTO LTS–6, Standard Specifications for Structural Supports for Highway Signs, Luminaires, and Traffic Signals, 6th Edition, copyright 2013, with:

(A) AASHTO LTS–6–I1, 2015 Interim Revisions to Standard Specifications for Structural Supports for Highway Signs, Luminaires, and Traffic Signals, copyright 2014.

(B) [Reserved]

(ix) AASHTO LRFDLTS–1, LRFD Specifications for Structural Supports for Highway Signs, Luminaires, and Traffic Signals, 1st Edition, copyright 2015, with:

(A) AASHTO LRFDLTS–1–I1–OL, 2017 Interim Revisions to LRFD Specifications for Structural Supports for Highway Signs, Luminaires, and Traffic Signals, copyright 2016, and

(B) AASHTO LRFDLTS–1–I2–OL, 2018 Interim Revisions to LRFD Specifications for Structural Supports for Highway Signs, Luminaires, and Traffic Signals, copyright 2017.

(x) 2017 Edition of Transportation Materials, Parts 1–3, copyright 2017.

(2) American Welding Society (AWS), 8669 NW 36 Street, #130 Miami, FL 33166–6672; *www.aws.org*; or (800) 443–9353 or (305) 443–9353.

* * * * *

[FR Doc. 2018–23821 Filed 10–31–18; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 4

RIN 2900–AO19

Schedule for Rating Disabilities: The Hematologic and Lymphatic Systems

Correction

In rule 2018–23517 beginning on page 54250 in the issue of Monday, October 29, 2018, make the following correction:

§ 4.117 [Corrected]

■ In § 4.117, On page 54255, in the table, entry 7703 should read as follows:

7703 Leukemia (except for chronic myelogenous leukemia):	
When there is active disease or during a treatment phase	100
Otherwise rate residuals under the appropriate diagnostic code(s).	
Chronic lymphocytic leukemia or monoclonal B-cell lymphocytosis (MBL), asymptomatic, Rai Stage 0	0
Note (1): A 100 percent evaluation shall continue beyond the cessation of any surgical therapy, radiation therapy, antineoplastic chemotherapy, or other therapeutic procedures. Six months after discontinuance of such treatment, the appropriate disability rating shall be determined by mandatory VA examination. Any change in evaluation based upon that or any subsequent examination shall be subject to the provisions of § 3.105(e) of this chapter. If there has been no recurrence, rate on residuals.	
Note (2): Evaluate symptomatic chronic lymphocytic leukemia that is at Rai Stage I, II, III, or IV the same as any other leukemia evaluated under this diagnostic code.	
Note (3): Evaluate residuals of leukemia or leukemia therapy under the appropriate diagnostic code(s). Myeloproliferative Disorders: (Diagnostic Codes 7704, 7718, 7719).	

[FR Doc. C1–2018–23517 Filed 10–31–18; 8:45 am]

BILLING CODE 1301–00–D

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 170817779–8161–02]

RIN 0648–XG477

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Catcher Vessels Greater Than or Equal to 60 Feet Length Overall Using Pot Gear 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 Pacific cod by catcher vessels greater than or equal to 60 feet (18.3 meters (m)) length overall (LOA) using pot gear in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the 2018 Pacific cod total allowable catch allocated to catcher vessels greater than or equal to 60 feet (18.3m) LOA using pot gear in the BSAI.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), October 30, 2018, through 1200 hours, A.l.t., December 31, 2018.

FOR FURTHER INFORMATION CONTACT: Josh Keaton, 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 2018 Pacific cod total allowable catch (TAC) allocated to catcher vessels greater than or equal to 60 feet (18.3m) LOA using pot gear in the BSAI is 15,235 metric tons (mt) as established by the final 2018 and 2019 harvest specifications for groundfish in the BSAI (89 FR 8365, February 27, 2018).

In accordance with § 679.20(d)(1)(iii), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the 2018 Pacific cod TAC allocated as a directed fishing allowance to catcher vessels greater than or equal to 60 feet (18.3m) LOA using pot gear in the BSAI will soon be reached. Consequently, NMFS is prohibiting directed fishing for Pacific cod by catcher vessels greater than or

equal to 60 feet (18.3m) LOA using pot gear in the BSAI.

While this closure is effective 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 closure of directed fishing for Pacific cod by catcher vessels greater than or equal to 60 feet (18.3m) LOA using pot gear 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 October 26, 2018.

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: October 29, 2018.

Karen H. Abrams,

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

[FR Doc. 2018–23909 Filed 10–29–18; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 83, No. 212
Thursday, November 1, 2018

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

DEPARTMENT OF ENERGY

10 CFR Parts 430 and 431

Energy Conservation Program: Energy Conservation Standards for Residential Furnaces and Commercial Water Heaters, Notice of Petition for Rulemaking

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

ACTION: Notice of petition for rulemaking; request for comment.

SUMMARY: On October 18, 2018, the Department of Energy (DOE) received a petition from the American Public Gas Association (APGA), Spire, Inc., the Natural Gas Supply Association (NGSA), the American Gas Association (AGA), and the National Propane Gas Association (NPGA), collectively referred to as the ''Gas Industry Petitioners,'' asking DOE to: Issue an interpretive rule stating that DOE's proposed energy conservation standards for residential furnaces and commercial water heaters would result in the unavailability of ''performance characteristics'' within the meaning of the Energy Policy and Conservation Act of 1975, as amended (*i.e.,* by setting standards which can only be met by condensing combustion technology products/equipment and thereby precluding the distribution in commerce of non-condensing combustion technology products/equipment) and withdraw the proposed energy conservation standards for residential furnaces and commercial water heaters based upon such findings. Through this notice, DOE seeks comment on the petition, as well as any data or information that could be used in DOE's determination whether to proceed with the petition.

DATES: Written comments and information are requested on or before January 30, 2019.

ADDRESSES: Interested persons are encouraged to submit comments, identified by ''Energy Conservation Standards for Residential Furnaces and Commercial Water Heaters,'' by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

E-mail: ResFurnaceCommWaterHeater2018STD0018@ee.doe.gov. Include Docket No. EERE–2018–BT–STD–0018 in the subject line of the message.

Postal Mail: Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, Mailstop EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. If possible, please submit all items on a compact disc (CD), in which case it is not necessary to include printed copies.

Hand Delivery/Courier: Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, 950 L'Enfant Plaza SW, Suite 600, Washington, DC 20024. Telephone: (202) 287–1445. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

Docket: For access to the docket to read background documents, or comments received, go to the Federal eRulemaking Portal at: *http://www.regulations.gov/docket?D=EERE-2018-BT-STD-0018.*

FOR FURTHER INFORMATION CONTACT: Mr. Eric Stas, U.S. Department of Energy, Office of the General Counsel, 1000 Independence Avenue SW, Washington, DC 20585. Telephone: (202) 586–9507. E-mail: *Eric.Stas@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: The Administrative Procedure Act (APA), 5 U.S.C. 551 *et seq.,* provides among other things, that ''[e]ach agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.'' (5 U.S.C. 553(e)) DOE received a petition from the Gas Industry Petitioners, as described in this notice and set forth verbatim below, requesting that DOE: (1) Issue an interpretive rule stating that DOE's proposed energy conservation standards for residential furnaces and commercial water heaters would result in the unavailability of ''performance characteristics'' within the meaning of the Energy Policy and Conservation Act of 1975 (42 U.S.C. 6291 *et seq.;* EPCA), as amended (*i.e.,* by setting standards which can only be met by condensing combustion technology products/equipment and thereby precluding the distribution in commerce of non-condensing combustion technology products/equipment) and (2) withdraw the proposed energy conservation standards for residential furnaces and commercial water heaters based upon such findings. In promulgating this petition for public comment, DOE is seeking views on whether it should grant the petition and undertake an interpretive rulemaking and withdrawal of the two specified rulemaking proposals, as requested. By seeking comment on whether to grant this petition, DOE takes no position at this time regarding the merits of the suggested rulemaking or the assertions made by the Gas Industry Petitioners.

In their petition, the Gas Industry Petitioners argue that DOE misinterpreted its mandate under section 325(o)(4) of EPCA by failing to consider as a ''feature'' of the subject residential furnaces and commercial water heating equipment the compatibility of a product/equipment with conventional atmospheric venting systems and the ability to operate without generating liquid condensate requiring disposal via a plumbing connection. Consequently, the Gas Industry Petitioners assert that DOE's proposals would make unavailable non-condensing products/equipment with such features, which currently exist in the marketplace, in contravention of the statute. The petition makes a number of technical, legal, and economic arguments in favor of its proposed interpretation, and it points to DOE's past precedent related to space constraints and differences in available electrical power supply (and associated installation costs) as supporting its call to find that non-condensing technology amounts to a performance-related ''feature.'' Based upon these arguments, the Gas Industry Petitioners conclude that DOE should issue an interpretive rule treating non-condensing technology as a ''feature'' under EPCA, withdraw its rulemaking proposals for both residential furnaces and commercial water heaters, and proceed on the basis of this revised interpretation.

DOE welcomes comments and views of interested parties on any aspect of the petition for rulemaking.

Submission of Comments

DOE invites all interested parties to submit in writing by January 30, 2019 comments and information regarding this petition.

Submitting comments via http://www.regulations.gov. The *http://www.regulations.gov* webpage will require you to provide your name and contact information prior to submitting comments. Your contact information will be viewable to DOE Building Technologies staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. Persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to *http://www.regulations.gov* information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information (CBI)). Comments submitted through *http://www.regulations.gov* cannot be claimed as CBI. Comments received through the website will waive any CBI claims for the information submitted. For information on submitting CBI, see the Confidential Business Information section.

DOE processes submissions made through *http://www.regulations.gov* before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that *http://www.regulations.gov* provides after you have successfully uploaded your comment.

Submitting comments via email, hand delivery, or postal mail. Comments and documents via email, hand delivery, or postal mail will also be posted to *http://www.regulations.gov.* If you do not want your personal contact information to be publicly viewable, do not include it in your comment or any accompanying documents. Instead, provide your contact information on a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments.

Include contact information in your cover letter each time you submit comments, data, documents, and other information to DOE. If you submit via postal mail or hand delivery, please provide all items on a CD, if feasible, in which case it is not necessary to submit printed copies. No telefacsimiles (faxes) will be accepted.

Comments, data, and other information submitted electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, written in English, and free of any defects or viruses. Documents should not include any special characters or any form of encryption, and, if possible, they should carry the electronic signature of the author.

Campaign form letters. Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters' names compiled into one or more PDFs. This reduces comment processing and posting time.

Confidential Business Information. Pursuant to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email, postal mail, or hand delivery two well-marked copies: one copy of the document marked ''Confidential'' including all the information believed to be confidential, and one copy of the document marked ''Non-confidential'' with the information believed to be confidential deleted. Submit these documents via email or on a CD, if feasible. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

Factors of interest to DOE when evaluating requests to treat submitted information as confidential include: (1) A description of the items; (2) whether and why such items are customarily treated as confidential within the industry; (3) whether the information is generally known by or available from other sources; (4) whether the information has previously been made available to others without obligation concerning its confidentiality; (5) an explanation of the competitive injury to the submitting person which would result from public disclosure; (6) when such information might lose its confidential character due to the passage of time, and (7) why disclosure of the information would be contrary to the public interest.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

DOE considers public participation to be a very important part of its process for considering rulemaking petitions. DOE actively encourages the participation and interaction of the public during the comment period. Interactions with and between members of the public provide a balanced discussion of the issues and assist DOE in determining how to proceed with a petition. Anyone who wishes to be added to DOE mailing list to receive future notices and information about this petition should contact Appliance and Equipment Standards Program staff at (202) 287–1445 or via e-mail at *ApplianceStandardsQuestions@ee.doe.gov.*

Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this notice of petition for rulemaking.

Signed in Washington, DC, on October 25, 2018.

Kathleen B. Hogan,

Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

October 18, 2018

BEFORE THE OFFICE OF ENERGY EFFICIENCY AND RENEWABLE ENERGY UNITED STATES DEPARTMENT OF ENERGY WASHINGTON, D.C.

Petition for Rulemaking

Energy Conservation Program: Energy Conservation Standards for Residential Furnaces

Docket Number EERE–2014–BT–STD–031; RIN No. 1904–AD20

Energy Conservation Program:

Energy Conservation Standards for Commercial Water Heaters

Docket Number EERE–2014–BT–STD–042; RIN No. 1904–AD34

Introduction

The undersigned organizations submit this petition for rulemaking under 5 U.S.C. § 553(e). As explained below, we request that the Department of Energy (''DOE''):

- Issue an interpretive rule confirming that energy conservation standards effectively limiting the market for natural gas and/or propane gas (''fuel gas'') furnaces or water heaters to products using condensing combustion technology would result in the unavailability of ''performance characteristics'' within the meaning of the Energy Policy and Conservation Act of 1975, as amended (''EPCA''), 42 U.S.C. § 6291 *et seq.,* and, consistent with that determination,
- Withdraw its proposed standards for residential furnaces and commercial water heaters on the grounds of appropriate written findings as specified by 42 U.S.C. §§ 6295(0)(4) and 6313(a)(6)(B)(iii)(II), respectively.[1]

We believe that these actions would appropriately resolve issues that have already contributed to delays in both the residential furnace and commercial water heater rulemaking proceedings, thereby facilitating a more orderly and efficient resolution of the remaining issues in these proceedings.

The basis for this petition is straight forward. The compatibility of a product with conventional atmospheric venting systems is an important product feature, as is the ability of a product to operate without generating liquid condensate requiring disposal *via* a plumbing connection. Residential furnaces and commercial water heaters that provide these features are generally available in the United States now. Products that use condensing combustion technology (''condensing products'') lack either one of these features. Efficiency standards that can only be achieved through the use of condensing combustion technology would therefore have the effect of rendering products with these features unavailable in the United States, a circumstance that EPCA was specifically designed to preclude.

EPCA expressly provides that DOE:

> may not prescribe an amended standard . . . if the Secretary finds (and publishes the finding) that interested persons have demonstrated by a preponderance of the evidence that a standard is likely to result in the unavailability in the United States or any product type (or class) of performance characteristics (including reliability, features, sizes, capacities, and volumes) that are substantially the same as those generally available in the United States at the time of the finding of the Secretary.[2]

There are no material facts in dispute. In both the residential furnace and commercial water heater rulemaking proceedings,[3] interested parties have demonstrated by a preponderance of the evidence—and DOE has itself acknowledged [4]—that:

- The standards proposed for residential furnaces and commercial water heaters (with a limited exception for certain ''small'' residential furnaces) can only be achieved by condensing products;
- Condensing products lack both the ability to function with atmospheric venting systems and the ability to function without generating liquid condensate requiring disposal *via* a plumbing connection;
- Products that have the ability to function with atmospheric venting systems and without generating liquid condensate requiring disposal *via* a plumbing connection are currently available in the United States; and
- Standards that can be achieved only by condensing products would make such products unavailable.

The only issue to be resolved is whether the product features at issue are ''performance characteristics'' for purposes of 42 U.S.C. §§ 6295(0)(4) and 6313(a)(6)(B)(iii)(II), and they plainly are.[5] Accordingly, DOE should issue an interpretive rule confirming that this is the case, and—consistent with that determination—should withdraw its proposed standards for residential furnaces and commercial water heaters on the basis of appropriate written findings pursuant to 42 U.S.C. §§ 6295(0)(4) and 6313(a)(6)(B)(iii)(II), respectively.

Features Precluded by the Use of Condensing Combustion Technology

Conventional fuel gas products are designed for atmospheric venting, typically through vent systems that carry exhaust gases, via buoyancy, vertically through the roof of the buildings in which they are installed. The vast majority of existing buildings and homes in which fuel gas products are installed in the United States were built with atmospheric venting systems designed to accommodate such products. Atmospherically-vented products are compatible with these existing venting systems (and with other atmospherically-vented products that use them); condensing products are not.

Gas products using condensing combustion technology provide increased thermal efficiency by extracting additional heat from combustion gases before they are vented. As a result, condensing products produce liquid condensate and cooler exhaust gases that lack sufficient buoyancy to exit a building via an atmospheric venting system. Condensing products therefore require plumbing for condensate disposal and ''power'' (*i.e.,* positive pressure) venting, typically through horizontal venting penetrating an exterior building wall.

Importantly, power-vented products *cannot share* common vent systems with atmospherically-vented products under the prevailing national model

[1] Standards for non-weatherized residential furnaces were published in a notice of proposed rulemaking at 80 Fed. Reg. 13120 (March 12, 2015) (''NOPR'') and in a supplemental notice of proposed rulemaking published at 81 Fed. Reg. 65720 (September 23, 2016) (Docket No. EERE–2014–BT–STD–0031); standards for commercial water heating equipment were published at 81 Fed. Reg. 34440 (May 31, 2016) (Docket No. EERE–2014–BT–STD–0042). Petitioners request that DOE withdraw all of the standards proposed in these two proceedings. The same issue is presented in the proposed rule for commercial packaged boiler energy conservation standards, Notice of Proposed Rulemaking and Announcement of Public Meeting, 81 Fed. Reg. 15836 (Mar. 24, 2016); litigation concerning that rulemaking is currently pending in the United States Court of Appeals for the Ninth Circuit. *NRDC* v. *Perry,* (Nos. 18–15380, 18–1545).

[2] 42 U.S.C. §§ 6295(0)(4) (applicable to residential furnaces) and 6313(a)(6)(B)(iii)(II) (identical provision applicable to commercial water heaters).

[3] *See* note 1.

[4] 81 Fed. Reg. 65720 at 65752–53 (Sept. 23, 2016) (residential furnaces); 81 Fed. Reg. 34440 at 34462–63 (May 31, 2016) (commercial water heating equipment). *Cf.* ''An Energy Revolution'' [an interview with DOE Secretary Perry] *American Gas* (October 2017) (''We are not going to pursue policies that tell businesses and consumers to choose one energy source over another. . . . The American people should be able to use the type of energy that they think is best for their businesses, their lives and their families.'').

http://read.nxtbook.com/aga/american_gas_magazine/american_gas_oct_2017/index.html?utm_source=twitter&utm_medium=social&utm_content=Oktopost-twitter-profile&utm_campaign=Oktopost-WGC+2018#an_energy_revolution

[5] *See* Joint Request for Interpretation, EERE–2014–BT–STD–0031 (filed June 6, 2017) at p. 3 (''It is absurd to suggest that features that may be necessary to make the use of a product practical (or even possible) are not ''performance-related features'' for EPCA purposes.). *See also* White Paper Developed by the American Gas Association and American Public Gas Association, ''In the Upcoming Rulemaking on Amendments to the Minimum Efficiency Standards for Non-Weatherized Residential Gas Furnaces, DOE Should Employ Separate Product Classes for Condensing and Noncondensing Furnaces'' (Oct. 22, 2014) (detailing the unique performance-related characteristics and consumer utility of non-condensing furnaces) (attached to Joint Request for Interpretation, supra).

codes.[6] Positive pressure in such a vent system would force combustion products into occupied spaces within the building through draft hoods and other atmospheric vent system structures. For this reason, safety standards and installation codes specifically separate vented fuel gas appliances and equipment into different categories based on their venting characteristics and specify that power-vented products cannot be connected to atmospheric venting systems or share common venting systems with atmospherically-vented gas products. In addition, condensing products require plumbing for condensate disposal that other vented gas products generally do not.

As further explained below and in comments submitted previously in the residential furnace and commercial water heater rulemaking proceedings, the features condensing products lack—compatibility with existing atmospheric venting systems and the ability to operate without a plumbing connection—are extremely important to consumers. Products with these features can be installed in locations inside buildings where condensing products cannot. Most significantly, non-condensing products can *replace* existing atmospherically-vented products without triggering the need for expensive building modifications or premature replacement of other commonly-vented gas products. Therefore, if these features were unavailable, there would be many cases in which it would be impractical to replace existing gas products with new gas products.

The Statutory Scheme, Precedent, and Application

Energy Policy and Conservation Act

Products that offer different features are often capable of achieving different measured efficiencies. Where this is the case, there is a potential that a particular efficiency standard could be achievable for products with some features but not achievable for products with other features, in which case the standard would effectively ban products with the latter features.

Congress anticipated such situations, and it made it clear that DOE is authorized to regulate product efficiency but *not to restrict the range of features that covered products can provide.* In fact, Congress expressly sought to ensure ''that energy savings are not achieved through the loss of significant consumer features.'' [7] EPCA expressly prohibits the adoption of an energy conservation standard if it has been shown that the standard would have the effect of eliminating a currently-available product feature from the market. 42 U.S.C. §§ 6295(o)(4) and 6313(a)(6)(B)(iii)(II). If DOE determines that a more stringent standard would be appropriate for products with specific product features, it can impose such standards *for products with those features.* Specifically, DOE can ''establish different standards within [a] type of covered product . . . based upon performance-related features of the product.'' [8] However, DOE can do this only by creating *separate product classes* for products with different performance-related features and specifying different (and achievable) standards for each. 42 U.S.C. § 6295(q)(1). This statutory scheme was expressly designed ''to ensure that an amended standard does not deprive consumers of product choices and characteristics, features, sizes, etc.,'' and to ''preclude'' the adoption of standards ''that manufacturers are only able to meet by adopting engineering changes that eliminate performance characteristics.'' [9] Unfortunately, that is exactly what DOE's proposed standards for residential furnaces and commercial water heaters would do.

Again, there is no dispute as to the relevant facts: DOE has acknowledged that its proposed efficiency standards can only be achieved through use of condensing combustion technology, and that those standards would effectively eliminate gas products that are compatible with atmospheric venting systems and do not require a plumbing connection.[10] DOE has simply suggested that the elimination of such products does not constitute a loss of product features for purposes of 42 U.S.C. §§ 6295(0)(4) and 6313(a)(6)(B)(iii)(II).[11] This suggestion is inconsistent both with EPCA's provisions and DOE's own previous determinations.

DOE Precedent

One of the ways in which DOE can avoid the adoption of standards that would eliminate available product features is to create separate product classes, with separate (and achievable) standards for products with those features.[12] In addressing the need for separate product classes, DOE has recognized again and again that features that significantly affect the conditions under which products can be used are *performance-related features* for EPCA purposes; *i.e.,* features that should be preserved rather than made ''unavailable'' by an energy conservation standard.

DOE has recognized different product classes for electric residential clothes dryers to address differences in product features concerning installation space constraints and differences in available electrical power supply.[13] Similarly, DOE's decision to maintain separate product classes for ''space-constrained'' heat pump and air conditioning products reflects the legal conclusion that product features that resolve significant installation constraints are *performance-related features* providing utility that other products lack.[14] The fact that DOE characterized the need to modify existing buildings to accommodate new products as a matter of ''installation cost'' did nothing to undermine that legal conclusion.[15] The

[6] ''National Fuel Gas Code, 2015 Edition,'' ANSI Z223.1/NFPA 54/, American Gas Association/National Fire Protection Association, 2015, and ''International Fuel Gas Code,'' International Code Council/American Gas Association, 2015.

[7] H.R. Rep. No. 100–11, 22 (1987).

[8] National Energy Conservation Act 1978, H.R. Rep. 95–1751, 115 (1978).

[9] H.R. Rep. No. 100–11, 23 (1987).

[10] *See* 81 Fed. Reg. 65720 at 65752–53 (Sept. 23, 2016) (residential furnaces); 81 Fed. Reg. 34440 at 34462–63 (May 31, 2016) (commercial water heating equipment).

[11] Furnace SNOPR, 81 Fed. Reg. at 65752. This suggestion dates back to the vacated Direct Final Rule, Energy Conservation Program: Energy Conservation Standards for Residential Furnaces and Residential Central Air Conditioners and Heat Pumps, 76 Fed. Reg. 37407, (June 27, 2011) (''Direct Final Rule''). Under an April 24, 2014 order of the United States Court of Appeals for the District of Columbia Circuit approving a settlement among the parties including DOE, that rule (including but not limited to DOE's determination that residential furnaces constitute a single class of products for purposes of 42 U.S.C. 6295(q)(1)(B)) was vacated and remanded to DOE for notice and comment rulemaking. Thus, DOE agreed, and the court ordered, that DOE reconsider the question of whether condensing and non-condensing non-weatherized gas furnaces should be treated as separate product classes in future rulemaking covering these products. DOE's subsequent failure to appropriately resolve this issue has significantly complicated (and thus delayed) development of a final rule regarding residential furnace standards, and has been the subject of extensive adverse comment. *E.g.,* APGA Residential Furnace Comments at 6–11 (filed Nov. 22, 2016) (''DOE fails to address the line of contrary precedent that APGA brought to its attention.''); AGA Comments at 32–43 (filed Nov. 22, 2016) (''AGA's view is that the utility and performance characteristics of non-condensing furnaces do require the creation of a separate product class for non-condensing furnaces.'').

[12] *See* 42 U.S.C. § 6295(q)(1).

[13] 10 C.F.R. § 430.32(h)(3).

[14] *See* Direct Final Rule, 76 Fed. Reg. at 37446 (''Because physical size constraints for through-the-wall products continue to exist, DOE determined that continuation of the space-constrained product class is warranted.'').

[15] *Id.* at 37404 (''DOE believes that through-the-wall equipment intended for replacement applications can meet the definition of space-constrained products because they must fit into a pre-existing hole in the wall, and a larger through-the-wall unit would trigger a considerable increase

same legal conclusion is reflected in the provisions of EPCA itself: for example, EPCA provides separate product classes for residential direct heating equipment based on variations in the manner in which such products are designed to be installed.[16]

In light of these precedents, DOE's continued failure to acknowledge that standards effectively eliminating atmospherically-vented gas products would result in a loss of performance characteristics for purposes of 42 U.S.C. §§ 6295(0)(4) and 6313(a)(6)(B)(iii)(II) would be arbitrary and capricious.

Application

The ability of a product to function without a plumbing connection is a feature that is no less important than features that affect where products will fit, what type of wiring they require, or whether they are designed to be free-standing as opposed to being installed in a wall or a floor. The ability of a product to function with atmospheric venting is an even *more* important feature because *it enables products to be used as replacements for atmospheric-vented products without the need for building alterations or the risk of adverse impacts on other atmospheric-vented gas products tied to a common venting system.*

These product characteristics are very important to the pocketbooks of many American homeowners using natural gas. Many homes with a conventional gas furnace have a commonly-vented conventional gas water heater. If standards make atmospherically-vented furnaces unavailable, furnace replacement may result in venting problems for the commonly-vented water heater, with the result that a perfectly good water heater may need to be replaced as well.[17]

The importance of performance characteristics such as the ability of a product to operate with a building's existing infrastructure and other commonly-vented products cannot be dismissed on the grounds that the building could be modified and other appliances scrapped. It is unreasonable to characterize the lack of such performance characteristics as a mere matter of ''installation costs'' [18] or to dismiss them as such.[19] In any event, there are cases in which the features condensing products lack are necessary if a gas product is to be used at all. This can occur, for example, in scenarios involving multistory housing in which vented gas products are common-vented into a central venting system that serves multiple floors of residential units that are under different ownership. In such cases, the inability of a consumer to replace an atmospherically-vented product with another atmospherically-vented product would not merely present problems for the consumers involved; it could adversely affect the venting of common-vented products owned by other parties in the same building.

DOE's prior assertion that standards requiring the use of condensing combustion technology would not impose a loss of product ''features'' is based on two conflicting legal arguments. The first, as stated in the residential furnace rulemaking, is that ''the consumer utility of a furnace is that it provides heat to a dwelling, and the type of venting used for particular furnace technologies does not impact that utility.'' [20] One obvious problem with this argument is that it is wrong on the facts: atmospheric-venting does impact the ability of a furnace to provide heat to a dwelling, because there are some cases in which atmospherically-vented furnaces can be used and condensing products cannot. Another is factors that limit the circumstances under which products can reasonably be used—size, for example—plainly have an impact on the utility of a product and are unmistakably within the range of ''performance characteristics'' that standards may not make unavailable.[21]

The second argument (again as stated in the context of the residential furnace rulemaking) is that the only ''features'' that must be preserved are those that ''provide unique utility to consumers beyond the basic function of providing heat, which all furnaces perform.'' [22] The argument that a ''feature'' must have unique utility ''beyond the basic function'' of a product is obviously difficult to square with the argument that a ''feature'' must ''impact the ability of a [product] to provide'' that basic function. However, the most obvious problem is that there is simply no statutory basis to assert either that a feature must have ''unique utility'' or that such utility must somehow be ''beyond the basic function'' of the product. EPCA simply states that DOE may not impose standards if it has been shown that they would likely result in unavailability of currently-available ''performance characteristics (including reliability, features, sizes, capacities, and volumes).'' [23]

> The policy concern driving these meritless legal arguments has been stated by DOE as follows: Tying the concept of ''feature'' to a specific technology would effectively lock-in the currently existing technology as the ceiling for product efficiency and eliminate DOE's ability to address significant technological advances that could yield significant consumer benefits in the form of lower energy costs while providing the same functionality for the consumer.'' [24]

This policy concern is at odds with the policy judgment Congress made when it adopted the relevant statutory provisions. The limitations on DOE's authority to impose design choices on manufacturers and consumers were not just designed to ensure the continued availability of products having the same ''functionality,'' particularly if ''functionality'' means nothing more than the basic ability of a product to provide heat (or hot water, as the case may be). Instead, Congress expressly sought to ensure ''that energy savings are not achieved through the loss of significant consumer features.'' [25] Features such as the compatibility of a product with an existing building's venting system and appliances, as well as its ability to operate without the need for a plumbing connection, are unquestionably significant to consumers. Arguments to the contrary in the pending rulemaking proceedings amount to transparent attempts to justify exactly the kind of outcome

in the installation cost to accommodate the larger unit.'').

[16] *See* 42 U.S.C. § 6295(e)(3). *See also* Final Rule, Energy Conservation Program: Energy Conservation Standards for Ceiling Fans, 82 Fed. Reg. 6826, 6833 (Jan 19, 2017) (adopting 7 product classes: highly-decorative, belt-driven, very small-diameter, hugger, standard, high-speed small-diameter and large-diameter fans). *Cf.* 10 C.F.R. § 430.32(y) (separate the product classes for furnace fans for non-condensing and condensing furnaces; thus DOE distinguished between non-condensing and condensing furnaces as an appropriate basis for creating separate product classes under EPCA).

[17] Spire Residential Furnace SNOPR Comments (filed Jan. 6, 2017) (*https://www.regulations.gov/contentStreamer?documentId=EERE-2014-BT-STD-0031-0309&attachmentNumber=1&contentType=pdf*) (open the PDF document and use the search function for the word ''stranded'').

[18] *See* 81 Fed. Reg. at 65753.

[19] *Id.* at 37404 (''DOE believes that through-the-wall equipment intended for replacement applications can meet the definition of space-constrained products because they must fit into a pre-existing hole in the wall, and a larger through-the-wall unit would trigger a considerable increase in the installation cost to accommodate the larger unit.'').

[20] 81 Fed. Reg. at 65752.

[21] *See* 42 U.S.C. § 6295(0)(4) (expressly including ''sizes''—apart from ''capacities or volumes''—among the examples of ''performance characteristics'' that cannot be made unavailable).

[22] 81 Fed. Reg. at 65753.

[23] 42 U.S.C. §§ 6295(0)(4) and 6313(a)(6)(B)(iii)(II).

[24] 81 Fed. Reg. at 65752 (residential furnaces); 81 Fed Reg. at 23363 (commercial water heaters).

[25] H.R. Rep. No. 100–11, 22 (1987).

Congress intended to preclude: the adoption of standards that would achieve higher efficiency by eliminating currently available ''performance characteristics'' (including ''features'') that are important to many purchasers.

Conclusion

DOE's rulemaking proceedings concerning standards for residential furnaces and commercial water heaters have been fatally undermined by their failure to recognize that EPCA precludes the adoption of standards that would effectively eliminate fuel gas products that do not use condensing combustion technology. Petitioners believe that prompt action to correct that failure is both warranted and necessary to facilitate any reasonably efficient path forward in those rulemaking proceedings. Accordingly, Petitioners respectfully request that DOE—after soliciting and appropriately considering public comment on this Petition—promptly take final action by:

- Issuing an interpretive rule confirming that energy conservation standards limiting the market for natural gas and/or propane gas furnaces or water heaters to products using condensing combustion technology would result in the unavailability of ''performance characteristics'' within the meaning of 42 U.S.C. §§ 6295(0)(4) and 6313(a)(6)(B)(iii)(II), and
- Withdrawing its proposed standards for residential furnaces and commercial water heaters on the grounds of appropriate written findings as specified by 42 U.S.C. §§ 6295(0)(4) and 6313(a)(6)(B)(iii)(II), respectively.

Further deliberation in the two pending rulemaking proceedings can then occur, with appropriate consideration—as EPCA requires—of any need for separate standards (and separate product classes) for products that use condensing combustion technology and those that do not.[26]

Respectfully submitted,

Mark Darrell,
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[FR Doc. 2018–23885 Filed 10X–31–18; 8:45 am]

BILLING CODE 6450–01–P

[26] *See* 42 U.S.C. § 6295(q)(1).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 112

[Docket No. FDA–2018–D–3631]

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Draft Guidance for Industry; Public Meetings; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public meetings; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing four public meetings to discuss ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Draft Guidance for Industry.'' The purpose of the public meetings is to discuss the draft guidance for compliance and implementation of the ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption'' rule, which was issued under the FDA Food Safety Modernization Act.

DATES: Submit either electronic or written comments on the notice by April 22, 2019. See ''How to Participate in the Public Meetings'' in the **SUPPLEMENTARY INFORMATION** section of this document for dates and times of the public meetings, closing dates for advance registration, requesting special accommodations due to disability, and other information regarding meeting participation.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 22, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 22, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2018–D–3631 for ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Draft Guidance for Industry.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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:

For questions about registering for the meetings or to register by phone: Melissa Schroeder, SIDEM, 1775 Eye St. NW, Suite 1150, Washington, DC 20006, 240–393–2901, *EventSupport@Sidemgroup.com.*

For general questions about the public meetings or for special accommodations due to a disability: Juanita Yates, Center for Food Safety and Applied Nutrition (HFS–009), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1731, *Juanita.Yates@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

''The Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption'' rule (the produce safety rule, published in the **Federal Register** of November 27, 2015 (80 FR 74354) (*https://www.fda.gov/fsma*)) establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption. The rule is part of the Agency's ongoing efforts to implement the FDA Food Safety Modernization Act (FSMA; Pub. L. 111–353). FSMA also requires FDA to issue guidance for the safe production and harvesting of fresh produce (section 419(e)(1) of the FD&C Act (21 U.S.C. 350h(e)(1))) and to also conduct at least three public meetings in diverse geographical areas of the United States as part of an effort to conduct education and outreach regarding the guidance for interested stakeholders (section 419(e)(2) of the FD&C Act).

In the **Federal Register** of October 22, 2018 (83 FR 53196), we announced the availability of the ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Draft Guidance for Industry'' (*https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM623178.pdf*). The draft guidance provides information on and recommendations for compliance with the requirements of the produce safety rule, which produce and farms are covered by the rule, and whether certain produce or farms may be eligible for exemptions.

FDA is announcing a series of public meetings entitled ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Draft Guidance for Industry'' so that stakeholders can better evaluate and comment on the draft guidance. These meetings will be held during the formal comment period on the draft guidance.[1] All four public meetings will cover the same agenda items and are intended to facilitate and support the public's evaluation and commenting process.

While oral presentations [2] from specific individuals and organizations will be necessarily limited due to time constraints during the public meetings, stakeholders may submit electronic or written comments discussing any issues of concern to the administrative record (the docket) for the draft guidance (Docket No. FDA–2018–D–3631).

II. Purpose and Format of the Public Meetings

The purpose of the public meetings is to provide information and facilitate comment so that stakeholders can better evaluate and provide input on the draft guidance. We invite interested parties to provide information and offer comments related to the produce safety rule draft guidance. During the public meetings we will present information on the various chapters of the draft guidance: General provisions; personnel qualifications and training; health and hygiene; biological soil amendments of animal origin; domesticated and wild animals; growing, harvesting, packing, and holding activities on a farm; equipment, tools, buildings, and sanitation; records; and variances.[3] Stakeholder panels will provide discussion on the various issues. There will be an opportunity for questions, as well as an opportunity for open public comment.

III. How To Participate in the Public Meetings

There will be a total of four public meetings held in diverse geographical areas of the United States to provide persons in different regions an opportunity to comment on the draft guidance.

Table 1 provides information on participation in the public meetings.

[1] Under FDA's Good Guidance Practices regulation, anyone may comment on an FDA guidance document at any time (see 21 CFR 10.115(g)(5)).

[2] Requests to make oral presentations must be made in advance. Please see table 1 for deadlines to request making an oral presentation for each meeting.

[3] We have proposed to extend the compliance dates related to the requirements of subpart E of the produce safety rule, which addresses agricultural water, and have provided enforcement discretion until the finalization of that rulemaking (82 FR 42963, 42965; September 13, 2017). Accordingly, the draft guidance does not contain any recommendations related to subpart E, and agricultural water is not on the agenda for these public meetings. Also not on the agenda for these public meetings is the draft guidance issued in January 2017 entitled ''Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations.''

TABLE 1—INFORMATION ON PARTICIPATING IN THE PUBLIC MEETINGS AND ON SUBMITTING COMMENTS TO THE PRODUCE SAFETY RULE DRAFT GUIDANCE DOCKET

Activity	Date	Electronic address	Address	Other information
First public meeting	November 27, 2018; 8:30 a.m.–5 p.m.	.....	Hilton Portland Downtown, 921 SW Sixth Ave., Portland, OR 97204.	
View webcast	November 27, 2018; 8:30 a.m.–5 p.m.	Individuals who wish to participate by webcast are asked to preregister at *https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm*.	.....	The webcast will have closed captioning.
Advance registration.	by November 16, 2018.	*https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm*.	We encourage you to use electronic registration if possible [1].	There is no registration fee for the public meetings. Early registration is recommended because seating is limited.[1]
Request to make an oral presentation.	by November 9, 2018.	*https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm*.	Requests to make oral presentations must be made in advance to *https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm*.	
Submitting either electronic or written comments.	Submit comments by April 22, 2019.	*https://www.regulations.gov*	Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.	See **ADDRESSES** for information on submitting comments.
Request special accommodations due to a disability.	by November 9, 2018.	.....	See **FOR FURTHER INFORMATION CONTACT**.	
Second Public Meeting.	November 29, 2018; 8:30 a.m.–5 p.m..	.....	DoubleTree Suites by Hilton Anaheim Resort-Convention Center, 2085 S Harbor Blvd., Anaheim, CA 92802.	
View webcast	November 29, 2018; 8:30 a.m.–5 p.m.	Individuals who wish to participate by webcast are asked to preregister at *https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm*.	.....	The webcast will have closed captioning.
Advance registration.	by November 16, 2018.	*https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm*.	We encourage you to use electronic registration if possible [1].	There is no registration fee for the public meetings. Early registration is recommended because seating is limited.[1]
Request to make an oral presentation.	by November 9, 2018.	*https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm*.	Requests to make oral presentations must be made in advance to *https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm*.	
Submitting either electronic or written comments.	Submit comments by April 22, 2019.	*https://www.regulations.gov*	Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.	See **ADDRESSES** for information on submitting comments.
Request special accommodations due to a disability.	by November 9, 2018.	.....	See **FOR FURTHER INFORMATION CONTACT**.	
Third Public Meeting.	December 11, 2018; 8:30 a.m.–5 p.m.	.....	Hilton Albany, 40 Lodge St., Albany, NY 12207.	
View webcast	December 11, 2018; 8:30 a.m.–5 p.m.	Individuals who wish to participate by webcast are asked to preregister at *https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm*.	.....	The webcast will have closed captioning.
Advance registration.	by November 23, 2018.	*https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm*.	We encourage you to use electronic registration if possible [1].	There is no registration fee for the public meetings. Early registration is recommended because seating is limited.[1]
Request to make an oral presentation.	by November 16, 2018.	*https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm*.	Requests to make oral presentations must be made in advance to *https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm*.	
Submitting either electronic or written comments.	Submit comments by April 22, 2019.	*https://www.regulations.gov*	Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.	See **ADDRESSES** for information on submitting comments.
Request special accommodations due to a disability.	by November 16, 2018.	.....	See **FOR FURTHER INFORMATION CONTACT**.	
Fourth Public Meeting.	December 13, 2018; 8:30 a.m.–5 p.m.	.....	Embassy Suites Atlanta at Centennial Olympic Park, 267 Marietta St., Atlanta, GA 30313.	

TABLE 1—INFORMATION ON PARTICIPATING IN THE PUBLIC MEETINGS AND ON SUBMITTING COMMENTS TO THE PRODUCE SAFETY RULE DRAFT GUIDANCE DOCKET—Continued

Activity	Date	Electronic address	Address	Other information
View webcast	December 13, 2018; 8:30 a.m.–5 p.m.	Individuals who wish to participate by webcast are asked to preregister at *https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.*		The webcast will have closed captioning.
Advance registration.	by November 23, 2018.	*https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.*	We encourage you to use electronic registration if possible [1].	There is no registration fee for the public meetings. Early registration is recommended because seating is limited.[1]
Request to make an oral presentation.	by November 16, 2018.	*https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.*	Requests to make oral presentations must be made in advance to *https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.*	
Submitting either electronic or written comments.	Submit comments by April 22, 2019.	*https://www.regulations.gov*	Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.	See **ADDRESSES** for information on submitting comments.
Request special accommodations due to a disability.	by November 16, 2018.		See **FOR FURTHER INFORMATION CONTACT**.	

[1] You may also register via email, mail, or Fax. Please include your name, title, firm name, address, and phone and Fax numbers in your registration information and send to: Melissa Schroeder, SIDEM, 1775 Eye St. NW, Suite 1150, Washington, DC 20006, 240–393–4496, Fax: 202–495–2901, *EventSupport@Sidemgroup.com.* Onsite registration will be available at all four meetings, however, please note that if we have reached capacity, we will not be able to accommodate those who have not pre-registered.

IV. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at *https://www.regulations.gov.* You may also view the transcript at the Dockets Management Staff (see **ADDRESSES**).

Dated: October 26, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–23868 Filed 10–31–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket No. FDA–2018–F–3932]

Bonamar Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by Bonamar Corp., proposing that we amend our food additive regulations to provide for the safe use of sources of ionizing radiation to control food-borne pathogens in finfish and flatfish.

DATES: The food additive petition was filed on September 27, 2018.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this document into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Molly A. Harry, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1075.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5))), we are giving notice that we have filed a food additive petition (FAP 8M4822), submitted by Bonamar Corp., c/o Robert P. Smith, Department of Biological Sciences, Nova Southeastern University, 3301 College Ave., Fort Lauderdale, FL 33314. The petition proposes to amend the food additive regulations in § 179.26 (21 CFR 179.26) *Ionizing radiation for the treatment of food* to provide for the safe use of sources of ionizing radiation to control food-borne pathogens in: (1) Chilled or frozen raw finfish and flatfish; and (2) frozen, raw vacuum-packed finfish and flatfish.

The petitioner has claimed that this action is categorically excluded from the need to prepare an environmental assessment or an environmental impact statement under 21 CFR 25.32(j), because the petition requests approval for a source of irradiation which is a piece of permanent equipment intended for repeated use. In addition, the petitioner has stated that, to the petitioner's knowledge, no extraordinary circumstances exist. If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

Dated: October 29, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–23946 Filed 10–31–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 807, 1002, 1010, and 1040

[Docket Nos. FDA–2011–N–0070 and FDA–2016–N–2491]

RIN 0910–AG79 and 0910–AF87

Withdrawal of the Laser Products; Proposed Amendment to Performance Standard and the Electronic Submission of Labeling for Certain Home-Use Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; withdrawal.

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

announcing the withdrawal of two proposed rules that published in the **Federal Register**. These proposed rules are not currently considered viable candidates for final action. FDA is taking this action because these proposed rules need to be reconsidered based on public comments received and new information developed after the publication of the proposed rules.

DATES: As of November 1, 2018, the proposed rules published on June 24, 2013, at 78 FR 37723, and October 17, 2016, at 81 FR 71415 are withdrawn.

ADDRESSES: For access to the docket, 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: Madhusoodana Nambiar, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5518, Silver Spring, MD 20993–0002, 301–796–5837, *Madhusoodana.Nambiar@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In 1990, FDA began a process of periodically conducting comprehensive reviews of its regulation process, including reviewing the backlog of proposed rulemakings that had not been finalized. As FDA removed many proposed rules not finalized, the Agency implemented a process of reviewing existing proposed rules every 5 years.

As part of this process and the Agency's regulatory reform initiative, we continue to conduct reviews of existing proposed rules. The review determines if the proposals are outdated, unnecessary, or should be revised to reduce regulatory burden while allowing FDA to achieve our public health mission and fulfill statutory obligations.

As part of these efforts, FDA is withdrawing the following proposed rules:

Title of proposed rule	Publication date, **Federal Register** citation	Docket No.	Reason for withdrawal
1. Laser Products; Proposed Amendment to Performance Standard.	June 24, 2013, 78 FR 37723.	FDA–2011–N–0070	The proposed rule referenced an international performance standard. That international standard is now being revised to reflect advancements in technology. FDA wants to have the most current international standard as a reference before publishing a final rule on laser products.
2. Electronic Submission of Labeling for Certain Home-Use Medical Devices.	October 17, 2016, 81 FR 71415.	FDA–2016–N–2491	Several adverse comments challenged the proposed FDA-managed labeling database as being unduly burdensome on both FDA and on industry, without efficiently enhancing public health. Additionally, concerns regarding the proposed format and potential costs for industry to fully implement were also raised. Based on the adverse comments, this rulemaking would benefit from being withdrawn at this time and reconsidered. The Agency plans to reconsider its approach and solicit further public input at a future date.

The withdrawal of these proposals identified in this document does not preclude the Agency from reinstituting rulemaking concerning the issues addressed in the proposals listed in the chart. Should we decide to undertake such rulemakings in the future, we will re-propose the actions and provide new opportunities for comment. Furthermore, this withdrawal of the proposed rules is only intended to address the specific actions identified in this document, and not any other pending proposals that the Agency has issued or is considering. If you need additional information about the subject matter of the withdrawn proposed rules, you may review the Agency's website (*https://www.fda.gov*) for any current information on the matter.

Dated: October 29, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–23916 Filed 10–31–18; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 770

[EPA–HQ–OPPT–2018–0174; FRL–9984–14]

RIN 2070–AK47

Technical Issues—Formaldehyde Emission Standards for Composite Wood Products

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to amend the regulations promulgated in a final rule that published in the **Federal Register** on December 12, 2016, concerning formaldehyde emission standards for composite wood products. EPA is publishing these proposed amendments to address certain technical issues and to further align the final rule requirements with the California Air Resources Board (CARB) Airborne Toxic Control Measures (ATCM) Phase II program. Addressing these technical issues would add clarity for regulated entities. These revisions to the existing rule would also streamline compliance programs and help to ensure continued smooth transitions for supply chains to comply with the requirements associated with regulated composite wood products.

DATES: Comments must be received on or before December 3, 2018.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2018–0174, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please

follow the instructions at *http://www.epa.gov/dockets/contacts.html*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Todd Coleman, National Program Chemicals Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: 202–564–1208; email address: *coleman.todd@epa.gov*.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be affected by this proposed rule if you manufacture (including import), sell, supply, offer for sale, test, or work with the certification of hardwood plywood, medium-density fiberboard, particleboard, and/or products containing these composite wood materials in the United States. 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:

- Veneer, plywood, and engineered wood product manufacturing (NAICS code 3212).
- Manufactured home (mobile home) manufacturing (NAICS code 321991).
- Prefabricated wood building manufacturing (NAICS code 321992).
- Furniture and related product manufacturing (NAICS code 337).
- Furniture merchant wholesalers (NAICS code 42321).
- Lumber, plywood, millwork, and wood panel merchant wholesalers (NAICS code 42331).
- Other construction material merchant wholesalers (NAICS code 423390), *e.g.,* merchant wholesale distributors of manufactured homes (*i.e.,* mobile homes) and/or prefabricated buildings.
- Furniture stores (NAICS code 4421).
- Building material and supplies dealers (NAICS code 4441).
- Manufactured (mobile) home dealers (NAICS code 45393).
- Motor home manufacturing (NAICS code 336213).
- Travel trailer and camper manufacturing (NAICS code 336214).
- Recreational vehicle (RV) dealers (NAICS code 441210).
- Recreational vehicle merchant wholesalers (NAICS code 423110).
- Engineering services (NAICS code 541330).
- Testing laboratories (NAICS code 541380).
- Administrative management and general management consulting services (NAICS code 541611).
- All other professional, scientific, and technical services (NAICS code 541990).
- All other support services (NAICS code 561990).
- Business associations (NAICS code 813910).
- Professional organizations (NAICS code 813920).

If you have any questions regarding the applicability of this action, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html*.

II. Background

A. Comments Received on Technical Issues

1. Stakeholder Feedback. Since the formaldehyde emission standards for composite wood products final rule (*see* 89 FR 89674) was promulgated on December 12, 2016, EPA has received letters, inquiries, and general correspondence from industry stakeholders, including the Composite Panel Association, Hardwood Plywood Veneer Association, Kitchen Cabinet Manufacturers Association, and various EPA recognized TSCA Title VI Third Party Certifiers (TSCA Title VI TPCs), regarding a number of technical issues with the testing and certification provisions of the rule. Stakeholders have requested EPA consider amending certain provisions of the TSCA Title VI regulations to improve regulatory clarity and further align the rule with the California Air Resources Board (CARB) Airborne Toxic Control Measures (ATCM) Phase II program. Correspondence from these industry stakeholders is included in the Supporting Documents section of the docket for this action.

The Agency has taken other actions since publication of the December 12, 2016 final rule to address other issues, including allowing early labeling of compliant composite wood products (*see* 82 FR 31922), extending the compliance dates in the December 12, 2016 final rule (*see* 82 FR 44533 and 83 FR 14375), and updating several voluntary consensus standard versions as well as the equivalence provisions between the American Society for Testing and Materials (ASTM) E1333–14 and ASTM D6007–14 test chambers (*see* 82 FR 5340).

2. June 28, 2018 Public Meeting on the Technical Issues. On May 24, 2018, the Agency published a notice in the **Federal Register** (*see* 83 FR 24104) announcing a public meeting at the EPA headquarters office in Washington, DC (with remote access available) on June 28, 2018 to discuss and obtain input on the technical issues that stakeholders have raised since the December 12, 2016 final rule. The publication of this notice also opened a 60-day public comment period to allow the public time to submit any additional data, information, or comments for the Agency to consider in developing this proposal.

During the June 28, 2018 public meeting, the Agency presented 11 technical issues and provided registered attendees the opportunity to comment on each issue and raise any additional issues before the conclusion of the meeting that had not been discussed. A transcript of this public meeting, letters, correspondence, and background materials are also posted in the Supporting Documents section of the docket for this action.

The Agency received 8 comments during the 60-day comment period opened for the public meeting. Those comments, in addition to the attendee feedback during the June 28, 2018 public meeting and the previously submitted letters and correspondence following the December 12, 2016 final

rule, have resulted in the identification of technical issues that the Agency is considering and, in most cases, addressing, by proposing to amend the TSCA Title VI regulations in this proposed rule.

Because the Agency has already taken public comment for 60 days on the majority of technical issues after the **Federal Register** notice announcing the public meeting (*see* 83 FR 24104) and given that the commenters were generally supportive of these changes, the comment period for this proposed action will be 30 days. Furthermore, the Agency is considering the use of an immediate or 15-day effective date upon publication of the final rule to provide regulated stakeholders time to adjust their certification programs before, or as close as possible to the March 22, 2019 TSCA Title VI rule's CARB reciprocity end date (*see* 83 FR 14375). Certain of the technical issues being proposed in this action would further align the TSCA Title VI program with the CARB ATCM Phase II program and streamline compliance for those entities currently certifying under CARB's program. Stakeholders have noted that having the effective date for these amendments at or before the March 22, 2019 TSCA Title VI rule's CARB Reciprocity date will ensure TPC program consistency and provide regulatory certainty as those programs can continue to operate as they have for years under the CARB ATCM Phase II program.

B. What action is the Agency taking?

a. Experimental resins and mill start-up and restart scenarios. The Agency is aware that the final rule does not directly discuss provisions for composite wood product mills that are starting up new operations, or mills that are restarting operations after a cessation in production, which would require working with a TSCA Title VI TPC to establish new correlations for producing what was a previously certified product. Stakeholders asked about this issue and requested the Agency provide guidance on it in addition to guidance on a path for products transitioning from research and development to regulated composite wood products.

On June 1, 2018, to address these two issues, the EPA posted guidance in the form of frequently asked questions on the Agency's formaldehyde homepage (Ref 1). In these frequently asked questions, the Agency outlined an example approach that could lead to prompt certification of composite wood products for start-up or restarting mills and products transitioning from research and development to be certified under the existing testing and certification provisions of the rule. The Agency received comments from a few stakeholders (*see* EPA–HQ–OPPT–2018–0174–0018, EPA–HQ–OPPT–2018–0174–0020, and EPA–HQ–OPPT–2018–0174–0022) requesting the Agency to provide more example approaches in the frequently asked questions. Stakeholders noted that there are other scenarios that could be used which are not directly identified in the existing frequently asked questions. EPA understands the issue and notes that the example approach used in the existing frequently asked questions is just one of many possible approaches which would be permitted under the TSCA Title VI regulations. So long as the TSCA Title VI TPC and panel producer are establishing a certification program that complies with the TSCA Title VI regulations, any such ''example'' or ''optional'' approach could be used. It is the Agency's understanding that there could be numerous mill start up and restart scenarios, which would be a challenge to accurately capture and develop rule provisions for without being inadvertently limiting in some way. The Agency believes the existing rule provisions and guidance it has already provided in the frequently asked questions are adequate and flexible enough to allow mills and TSCA Title VI TPCs to use their expertise and work together to develop timely approaches that are tailored to their specific scenarios and that ensure the manufacture of composite wood products which are compliant with the rule. Accordingly, EPA is not proposing new rule provisions for mill start-up and restarts, or the use of new or otherwise experimental resins.

b. Annual correlations between the third-party certifier ASTM E1333 or equivalent ASTM D6007 apparatus and any other mill quality control testing method. EPA is proposing to amend the rule by removing the requirement for annual correlations at § 770.20(d). The rule currently requires a showing of correlation between the TSCA Title VI TPC's ASTM E1333–14 apparatus (or contract laboratory's ASTM E1333–14 apparatus) or equivalent ASTM D6007–14 apparatus and any other mill quality control testing methods at § 770.20(b) on an annual basis for the first three years after initial correlation establishment, and every two years thereafter to continue certifying composite wood products. The CARB ATCM Phase II program does not require annual correlations between the TPC (or contract laboratory) ASTM E1333–14 apparatus or equivalent ASTM D6007–14 apparatus and any other approved method for quality control testing. The CARB ATCM Phase II program requires that an initial correlation be established between the ASTM E1333–14 apparatus (or contract laboratory's ASTM E1333–14 apparatus) or equivalent ASTM D6007–14 apparatus and any other approved method for quality control testing, and then be reestablished only when there is a significant change in the operation at the mill or when there is a reason to believe the correlation is no longer valid. Stakeholders have requested that EPA amend § 770.20(d) to align with the CARB ATCM Phase II correlation requirement. CARB's ATCM requires panel producers to work with a TPC to develop an initial correlation. CARB staff have noted that requiring subsequent correlations only on an as-needed basis (rather than requiring that a correlation be redeveloped annually) has not reduced the quality of testing data or composite wood products meeting the emission standard under the CARB ATCM Phase II program. CARB staff have also noted that should there be any issue with the validity of the correlation, the panel producer and TPC would notice immediately as the results from quarterly and quality control testing would vary considerably from what would be expected for any given product type being tested. Stakeholders as well have expressed that the removal of the annual correlation requirement would result in a streamlined path to compliance while having no negative affect on the validity of the test data received from either the TSCA Title VI TPC's testing apparatus nor the mill quality control testing method at § 770.20(b).

c. Equivalence or correlation on like-size or similar sized apparatuses. EPA is proposing an amendment to § 770.20(d) to allow the TSCA Title VI TPC to use their ASTM E1333–14 apparatus (or their contract laboratory's ASTM E1333–14 apparatus) to demonstrate equivalence to multiple ASTM D6007–14 apparatuses of a similar model or size and construction located in the same TSCA Title VI TPC laboratory, or contract laboratory. Similar model chambers would be those that are manufactured by the same manufacturer and bear the same model number or bear a model number that succeeds a previous model number that has been discontinued or otherwise is no longer being manufactured but would be deemed the equivalent by the manufacturer. Similar size and construction chambers would have an identical chamber volume capacity and be constructed in a way that would

result in the same sample holding capacity and operational parameters (*e.g.,* airflow speed, time to conduct testing, etc.) as another chamber, but need not be made by the same manufacturer. The Agency understands that CARB has allowed a similar approach under the ATCM Phase II program and there has been no negative impact on generation of data to demonstrate valid equivalence between test methods.

EPA is also proposing to update the correlation requirement at § 770.20(d) to allow multiple similar model or size and construction mill quality control test method apparatuses located at any one physical mill quality control testing laboratory to demonstrate correlation to the TSCA Title VI TPC test apparatus as required under § 770.20(d) in the same capacity as the amended equivalence allowance. Although not currently discussed in the CARB ATCM Phase II program, stakeholders note that some mills have multiple quality control testing apparatuses of the same or like model at each mill location, and being able to establish correlations to like model or size and construction apparatuses located at any one physical mill location would streamline compliance while having no impact on data quality and quality control testing. EPA is proposing to codify this interpretation of the TSCA Title VI regulation.

d. Averaging of emission test results during quarterly and non-complying lot testing. EPA is proposing to add subparagraph (iv) to § 770.20(c)(2) and amend subparagraph (i) at § 770.22(c)(2) to align with the CARB ATCM Phase II program regarding averaging test results during quarterly testing and non-complying lot retesting. CARB's approved method for test results averaging accounts for formaldehyde emission variability across any one composite wood product panel while ensuring the products still meet the applicable emission standards. CARB's method at 17 California Code of Regulations section 93120.9(a)(2)(A) and (B)(2) and Appendix 2 (g)(8) of its regulations includes allowing nine subsamples from any one panel to be collected and tested in an ASTM E1333–14 or equivalent ASTM D6007–14 apparatus in groups of three, resulting in three test values, which are then averaged to obtain one final value that accounts for emission variability across that one panel (Ref 2). Under these requirements, the nine subsamples should be evenly distributed and represent similar sizes to one another as they are collected from any one panel.

CARB does not address the averaging of test results for quality control testing in the ATCM program. EPA is not proposing an update to the quality control testing requirements; rather EPA is proposing to explicitly allow averaging of data generated for quarterly testing and non-complying lot retesting. EPA believes that this added clarity will assist TSCA Title VI TPCs and panel producers in testing composite wood products in the same capacity that they have been testing under the CARB ATCM, and that this amendment will not reduce test data quality.

e. Equivalence testing emission ranges. EPA is proposing to update the requirement at § 770.20(d) for TSCA Title VI TPCs to demonstrate equivalence under specified emission ranges. The CARB ATCM specifies that ten comparison tests must be conducted, consisting of at least five comparison tests in two of three specified emission ranges. CARB's ATCM at 17 California Code of Regulations section 93120.9(a)(2)(B)(3) specifies the three emission ranges as (1) low—for products demonstrating formaldehyde emissions of less than 0.07 parts per million (ppm); (2) intermediate—for products demonstrating formaldehyde emissions from 0.07 ppm to less than 0.15 ppm; and (3) upper—for products demonstrating formaldehyde emissions from 0.15 ppm to 0.25 ppm (Ref 2). The current TSCA Title VI regulation does not require demonstration of equivalence across separate emission ranges as the CARB ATCM Phase II program does; rather, the TSCA Title VI regulation requires that a minimum of five comparison sets are required to represent the range of product emissions a TPC expects to certify. EPA is proposing to align with CARB's ATCM and their requirement for ten comparison tests, consisting of five comparison tests in two of the three specified ranges (with a modification to the emission ranges and a modification to the requirement for demonstration across two ranges based on comments submitted by CARB) (*see* EPA–HQ–OPPT–2018–0174–0022).

First, in the proposed emission ranges for the equivalence comparison tests under the TSCA Title VI regulation, EPA proposes to modify the values for the emission ranges from the current guidance under the CARB ATCM Phase II program. EPA understands that CARB intends to update their low emission range by changing the value to formaldehyde emissions of less than or equal to 0.05 ppm, which would change the intermediate range as well. This emission range corresponds to the emission standard for hardwood plywood. EPA is aware of several TPCs who only certify hardwood plywood and would prefer only demonstrating equivalence in this range. EPA agrees that the low range should be reserved for products that demonstrate formaldehyde emissions of less than or equal to 0.05 ppm, and this will require a corresponding adjustment to the intermediate range, which would begin with the value of formaldehyde emissions greater than 0.05 ppm instead of the current 0.07 ppm and cover those products with emissions up to 0.15 ppm. The upper emission range would remain the same for TSCA Title VI TPCs and mills that choose to demonstrate equivalence of their apparatuses at this upper range.

The second modification EPA is proposing in the TSCA Title VI regulation regarding testing emission ranges, which is a deviation from the current guidance under the CARB ATCM Phase II program, involves the requirement for demonstration of equivalence across two ranges if the TSCA Title VI TPC will only certify composite wood products in either the low or intermediate range, but not both. Regulated composite wood products emitting formaldehyde at a value meeting the upper emission range would not be compliant with the emission standards under the TSCA Title VI regulation. EPA is proposing that those TSCA Title VI TPCs who will only certify in one range may demonstrate equivalence for that range only, using at least five comparison tests to demonstrate equivalence in that range. TPCs certifying in two ranges would be required to conduct at least five comparison tests in each range—for a minimum number of ten comparison tests. The TSCA Title VI TPC would be restricted to only certifying product in this emission range if they choose to only demonstrate equivalence in one range (*i.e.,* low, intermediate, or upper according to § 770.20(d)(1)(iv)(A) through (C)). EPA is proposing to codify this in the TSCA Title VI regulation.

f. Determination of equivalence only if mill uses TSCA Title VI TPC for all testing. EPA is proposing to amend § 770.20(d) to clarify that mills that do not perform any testing on-site at the mill and instead use their TSCA Title VI TPC for all quarterly and quality control testing would not be required to establish correlation as they are already using a TSCA Title VI TPC ASTM E1333–14 apparatus, or an ASTM D6007–14 apparatus that has demonstrated equivalence. Stakeholders have noted that when a panel producer uses the TSCA Title VI TPC for all

testing under the TSCA Title VI regulation, they are using either an ASTM E1333–14 or equivalent ASTM D6007–14 testing apparatus which as the rule is currently written could lead one to interpret that the test chamber must be correlated to itself. The EPA's posted guidance on this issue in the form of a frequently asked question on the Agency's formaldehyde homepage noted that the ASTM D6007–14 test apparatus that shows equivalence to the TSCA Title VI TPCs ASTM E1333–14 test apparatus according to § 770.20(d) would necessarily show correlation to itself under § 770.20(d)(2) and could be used as a quality control test method without additional correlation testing (Ref 1). EPA is proposing to codify this interpretation of the TSCA Title VI regulation.

g. Correlation coefficients and ''r'' values. EPA is proposing to amend § 770.20(d)(2) to expand the options for TSCA Title VI TPCs and mills in establishing correlation coefficients and ''*r*'' values beyond the linear regression model currently required by the TSCA Title VI regulations, in order to include the CARB ATCM Phase II approved cluster approach (also known as the point of origin approach in practice) and threshold approach. CARB's alternative correlation coefficient and ''*r*'' value method guidance document (CWP–10–001 [June 8, 2010]) outlines these two additional approaches for how TPCs certifying composite wood products under the CARB ATCM Phase II program may show correlation (Ref 3). EPA is proposing the addition of rule provisions for the ''cluster approach'' and ''threshold approach'' in § 770.20(d)(2)(i) and updating the requirement for certification at § 770.15(c)(1)(vii) and § 770.15(c)(2)(v). The addition of these approaches will aid TSCA Title VI TPCs in meeting the correlation requirements for manufacturers producing low formaldehyde-emitting products. Although the cluster approach uses the same linear regression line and ''r'' values listed at § 770.20(d)(2)(ii), the threshold approach does not. The threshold approach creates a ''do not exceed limit'' for composite wood products which provides a margin of safety relative to the maximum value of the data point clusters which are achieved through the use of the existing linear regression testing or the cluster approach.

h. Notifications of exceedance of quality control limit (QCL). EPA is proposing an amendment at § 770.7(c)(4)(v)(C) to clarify that notification of a non-complying lot through the EPA's Central Data Exchange system by a TSCA Title VI TPC will be required within 72 hours of the time when the TSCA Title VI TPC is notified of the third QCL exceedance by a panel producer. EPA views this as a minor editorial clarification that would amend the rule text such that the requirement reads the way EPA had originally intended.

i. No-added formaldehyde (NAF)-based resin and ultra-low-emitting formaldehyde (ULEF) resin testing requirements. EPA is proposing the amendment of the NAF and ULEF testing requirements to align with the CARB ATCM Phase II program. The TSCA Title VI final rule requires that under the NAF requirements at § 770.17 a minimum of five tests be conducted pursuant to the NAF two-year exemption application while CARB's TPC Bulletin 1 notes that 13 tests are the minimum permitted for a limited exemption (Ref 4). Additionally, the TSCA Title VI final rule requires that under the ULEF requirements at § 770.18, a minimum of ten tests be conducted pursuant to the ULEF two-year exemption or reduced testing application while CARB's TPC Bulletin 1 notes that 26 tests are the minimum permitted for a limited exemption (Ref 4). Stakeholders note that although EPA will accept existing CARB executive orders for NAF and ULEF products from panel producers in good standing as outlined in § 770.17(d) and § 770.18(e), the two programs are not equal in the number of samples required, and the CARB ATCM Phase II program requires more samples. To promote regulatory consistency between the two programs, the EPA is proposing to adopt the CARB-required 13 tests for NAF and 26 tests for ULEF applications under the TSCA Title VI NAF two-year exemption application and ULEF two-year exemption or reduced testing application. The Agency does not believe this amendment will alter in any significant way how TSCA Title VI TPCs and panel producers currently conduct testing under the CARB ATCM Phase II or TSCA Title VI program, as EPA allows the use of equal or more stringent testing approaches (*i.e.,* more tests) and it is EPA's understanding that TSCA Title VI TPCs have continued to conduct testing the same way they have done for years under the CARB ATCM Phase II program.

j. Voluntary Consensus Standards incorporated by reference at § 770.99. EPA is proposing to update the references for two International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) voluntary consensus standards that were incorporated by reference in the December 12, 2016 final rule. Although these standards have been updated since the December 12, 2016 final rule was published, they were updated after the Agency proposed to update other voluntary consensus standards in an October 25, 2017 notice of proposed rulemaking (*see* 82 FR 49302). Table 1 in this Unit outlines the voluntary consensus standards that would be updated in this proposal and the respective updated versions. All other standards in the formaldehyde emission standards for composite wood products regulations will continue to be incorporated by reference as they appear in the existing regulation.

TABLE 1—VOLUNTARY CONSENSUS STANDARDS COMPARISON

Current standard established by final rule (81 FR 89674)	Status	Update to be promulgated effective [30 days from publication of **Federal Register** notice of proposed rulemaking]
ISO/IEC 17025–2005(E) General requirements for the competence of testing and calibration laboratories.	Updated version	ISO/IEC 17025:2017(E) General requirements for the competence of testing and calibration laboratories.
ISO/IEC 17011–2004(E) Conformity assessments—General requirements for accreditation bodies accrediting conformity assessments bodies.	Updated version	ISO/IEC 17011:2017(E) Conformity assessments—requirements for accreditation bodies accrediting conformity assessments bodies.

EPA proposes to adopt the updated versions of the standards referenced in Table 1. Specifically, EPA proposes to revise the current references to sections 7.5 to 7.11 of the 2004 version of ISO/IEC 17011 to the corresponding sections 7.4 to 7.13 of the 2017 version. As well, EPA proposes to revise the current reference to section 7.11 of the 2004

version of ISO/IEC 17011 to the corresponding section 7.9 of the 2017 version. EPA also understands that stakeholders prefer to use the current versions of the standards in both regulatory and non-regulatory programs stakeholders are involved with in their capacity as accreditation bodies or TPCs. Any future versions or updates to withdrawn/superseded standards will be announced by EPA through a separate **Federal Register** document with opportunity for public comment.

k. Clarification in the non-complying lot provisions. Stakeholders requested clarity on the intent of the non-complying lot provisions at § 770.22 and how those provisions might apply to fabricators, importers, retailers or distributors who are notified by panel producers that a composite wood product they were supplied is found to be non-compliant after those composite wood products have been further fabricated into component parts or finished goods. The Agency previously posted guidance on this issue in the form of frequently asked questions on the Agency's formaldehyde homepage. The guidance outlines the requirements for all entities in the supply chain and makes clear that, if the panel is still in panel form, the entity in possession of the non-compliant panel is to work with the panel producer to isolate, treat, and retest the panels, as needed. If the panels from the non-complying lot have been incorporated into component parts or finished goods, the remainder of § 770.22 does not apply beyond when those panels were fabricated into the component parts or finished goods (Ref 5).

EPA notes that the regulatory intent behind the non-complying lot provisions at § 770.22 was to manage those non-compliant composite wood products in their panel form and not after those panels have been fabricated into component parts or finished goods. EPA understands that it would be a significant tracking burden for fabricators to determine exactly which component parts or finished goods those panels may have been fabricated into and, therefore, impractical from a chain of custody management approach. As such, the Agency proposes to include the clarifying guidance in § 770.22 to make clear the initial regulatory intent of the December 12, 2016 final rule and promote regulatory certainty.

l. Labels on regulated composite wood products and finished goods containing composite wood products at point of manufacture, fabrication, and/or import. EPA is proposing to clarify in § 770.45 that regulated composite wood products and finished goods containing composite wood products must be labeled at the point of manufacture or fabrication, and if imported, the label must be affixed to the product as a condition of entry into the port. Under TSCA, the term ''manufacture'' includes import, meaning that regulated composite wood products or finished goods containing such products imported into the customs territory of the U.S. must be accompanied at the time of import by a label as required by § 770.45 and this proposed amendment would just clarify this requirement. It is the Agency's understanding that industry currently interprets and implements the § 770.45 labeling provision as EPA originally intended (and is now proposing to clarify).

m. Labels on panels manufactured under NAF limited exemption at § 770.17 and ULEF limited exemption at § 770.18. EPA is proposing to clarify that panels manufactured under a limited exemption at § 770.17 and § 770.18 from certain final rule requirements or existing CARB executive orders for NAF and ULEF products from panel producers in good standing as outlined in § 770.17(d) and § 770.18(e) may be labeled as TSCA Title VI ''compliant'' and need not read ''certified.'' EPA understands that the regulatory language at § 770.45(a) requires the use of the term ''certified'' on composite wood products. For the purposes of panels made under a limited exemption at § 770.17 and § 770.18 or existing CARB executive orders, however, the use of the term ''compliant'' should be allowed as those panels have demonstrated they meet the emission standards and the exemption requirement; however, they are not ''certified'' in the same capacity that other composite wood products are due to the existing, limited exclusion from certification requirements under § 770.15 and § 770.40(b).

n. TSCA Title VI manufactured-by date. In the final rule, EPA also intends to conform the manufactured-by date in the Code of Federal Regulations to correspond to the manufactured-by date of June 1, 2018 resulting from the court order announced by EPA in a **Federal Register** notice on April 4, 2018 (*see* 83 FR 14375). Specifically, EPA intends to replace December 12, 2018 with June 1, 2018 in § 770.2(e) (introductory text), § 770.2(e)(1), § 770.2(e)(4), § 770.10(a), § 770.12(a), § 770.15(a), § 770.30(b) (introductory text), and § 770.30(c). For more information on the litigation and court order, please see 83 FR 14375.

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

These regulations are established under authority of section 601 of TSCA, 15 U.S.C. 2697.

III. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. U.S. Environmental Protection Agency. Frequent Questions about Starting-up New Composite Wood Mills and the Use of Experimental Products and Resins. 2018. *https://www.epa.gov/formaldehyde/frequent-questions-about-starting-new-composite-wood-mills-and-use-experimental.*
2. California Air Resources Board. Airborne Toxic Control Measure to Reduce Formaldehyde Emissions from Composite Wood Products. Final Regulation Order. April 2008.
3. California Air Resources Board. Third Party Certification Guideline: Establishing a Correlation with an Acceptable Correlation Coefficient (''*r*'', Value). June 2010. *https://www.arb.ca.gov/toxics/compwood/certifiers.htm.*
4. California Air Resources Board. Third Party Certifier Bulletin 1 (revised). August 2012. *https://www.arb.ca.gov/toxics/compwood/certifiers.htm.*
5. U.S. Environmental Protection Agency. Frequent Questions for Regulated Stakeholders about Implementing the Formaldehyde Standards for Composite Wood Products Act. 2018. *https://www.epa.gov/formaldehyde/frequent-questions-regulated-stakeholders-about-implementing-formaldehyde-standards.*

IV. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.epa.gov/laws-regulations/laws-and-executive-orders.*

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

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 and 13563.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is not an Executive Order 13771 regulatory action because this action is not significant under Executive Order 12866.

C. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA, 44 U.S.C. 3501 *et seq.,* because it does not create any new reporting or recordkeeping obligations. OMB has previously approved the information collection activities contained in the existing regulations and has assigned OMB control number 2070–0185.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601 *et seq.* In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden or otherwise has a positive economic effect on the small entities subject to the rule. As addressed in Unit II.A., this action would not significantly alter the TSCA Title VI regulations or supporting economic analysis for the December 12, 2016 final rule as published and will provide technical amendments to further align the EPA's TSCA Title VI program with the CARB ATCM Phase II program. This action will relieve or have no net regulatory burden for directly regulated small entities.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. This proposed rule would not impose substantial direct compliance costs on Indian tribal governments. Thus, Executive Order 13175 does not apply to this action.

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

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of Executive Order 13045 has the potential to influence the regulation. As addressed in Unit II.A., this action would not significantly alter the December 12, 2016 final rule as published and proposes technical amendments to further align the EPA's TSCA Title VI program with the CARB ATCM Phase II program.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR Part 51

This action involves technical standards. EPA is proposing the use of the following voluntary consensus standards issued by International Organization for Standardization/International Electrotechnical Commission:

1. ISO/IEC 17011:2017(E) Conformity assessments—requirements for accreditation bodies accrediting conformity assessments bodies.

2. ISO/IEC 17025:2017(E) General requirements for the competence of testing and calibration laboratories.

Copies of the standards referenced in the proposed regulatory text at § 770.3 and § 770.7 have been placed in the docket for this proposed rule. You may also obtain copies of these standards from the International Organization for Standardization, 1, ch. de la Voie-Creuse, CP 56, CH–1211, Geneve 20, Switzerland, or by calling +41–22–749–01–11, or at *http://www.iso.org.* Additionally, each of these standards is available for inspection at the OPPT Docket in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA, West Bldg., 1301 Constitution Ave. NW, Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. The following voluntary consensus standards are being updated: In the final rule, EPA intends to seek approval from the Director of the Federal Register for the incorporation by reference of the standards referenced in the final rule in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

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

EPA has determined that this action will not have potential disproportionately high and adverse human health or environmental effects on minority, low-income or indigenous populations, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The Agency presented the results of an environmental justice analysis in the December 12, 2016 TSCA Title VI final rule economic analysis (*see* EPA–HQ–OPPT–2016–0461–0028) and determined that the final rule did not have disproportionately high and adverse human health or environmental effects on minority, low-income or indigenous populations. This action would not significantly alter the final rule or the environmental justice analysis. The environmental justice analysis monetized the benefits from reducing the number of cases of nasopharyngeal cancer and sensory irritation and included an environmental justice analysis that expanded on the primary benefits analysis by analyzing the monetized impacts specifically for minority and low-income populations. This action will propose technical amendments to further align the EPA's TSCA Title VI program with the CARB ATCM Phase II program.

List of Subjects in 40 CFR Part 770

Environmental protection, Formaldehyde, Incorporation by reference, Reporting and recordkeeping requirements, Third-party certification, Toxic substances, Wood.

Dated: October 16, 2018.

Charlotte Bertrand,

Acting Principal Deputy Assistant Administrator.

Therefore, it is proposed that 40 CFR chapter I, subchapter R, of the Code of

Federal Regulations be amended as follows:

PART 770—[AMENDED]

■ 1. The authority citation for part 770 continues to read as follows:

Authority: 15 U.S.C. 2697(d).

■ 2. In § 770.2, revise paragraphs (e) introductory text and (e)(1) and (4) to read as follows:

§ 770.2 Effective dates.

(e) Beginning June 1, 2018, all manufacturers (including importers), fabricators, suppliers, distributors, and retailers of composite wood products, and component parts or finished goods containing these materials, must comply with this part, subject to the following:

(1) Beginning June 1, 2018, laminated product producers must comply with the requirements of this part that are applicable to fabricators.

* * * * *

(4) Composite wood products manufactured (including imported) before June 1, 2018 may be sold, supplied, offered for sale, or used to fabricate component parts or finished goods at any time.

* * * * *

§ 770.3 [Amended]

■ 3. In § 770.3:

■ a. In the terms ''Assessment,'' ''Reassessment,'' ''TPC Laboratory,'' ''Surveillance On-Site Assessment'' remove ''17011:2004(E)'' and add in its place ''17011:2017(E);'' and,

■ b. In the terms ''EPA TSCA Title VI Laboratory Accreditation Body or EPA TSCA Title VI Laboratory AB'' and ''TPC Laboratory,'' remove ''17025:2005(E)'' and add in its place ''17025:2017(E).''

■ 4. In § 770.7:

■ a. In paragraphs (a)(1)(ii), (a)(5)(ii), (b)(1)(ii), (b)(5)(ii) remove ''ISO/IEC 17011:2005(E)'' and add in its place ''ISO/IEC 17011:2017(E);'' and,

■ b. In paragraphs (a)(5)(i)(F), (b)(1)(iii), (b)(5)(i), (b)(5)(i)(A), (c)(1)(ii), (c)(2)(iv), remove ''ISO/IEC 17025:2005(E)'' and add in its place ''ISO/IEC 17025:2017(E);'' and,

■ c. Revise paragraph (c)(4)(v)(C).

The revision reads as follows:

§ 770.7 Third party certification.

* * * * *

(c) * * *

(4) * * *

(v) * * *

(C) Notification of a panel producer exceeding its established QCL for three consecutive quality control tests within 72 hours of the time that the TPC becomes aware of the third exceedance. The notice must include the product type, dates of the quality control tests that exceeded the QCL, quality control test results, ASTM E1333–14 (incorporated by reference, see § 770.99) or ASTM D6007–14 method (incorporated by reference, see § 770.99) correlative equivalent values in accordance with § 770.20(d), the established QCL value(s) and the quality control method used.

* * * * *

■ 5. In § 770.10, revise paragraph (a) to read as follows:

§ 770.10 Formaldehyde emission standards.

(a) Except as otherwise provided in this part, the emission standards in this section apply to composite wood products sold, supplied, offered for sale, or manufactured (including imported) on or after June 1, 2018 in the United States. These emission standards apply regardless of whether the composite wood product is in the form of a panel, a component part, or incorporated into a finished good.

* * * * *

■ 6. In § 770.12, revise paragraph (a) to read as follows:

§ 770.12 Stockpiling.

(a) The sale of stockpiled inventory of composite wood products, whether in the form of panels or incorporated into component parts or finished goods, is prohibited after June 1, 2018.

* * * * *

■ 7. In § 770.15, revise paragraphs (a), (c)(1)(vii) and (c)(2)(v) to read as follows:

§ 770.15 Composite wood product certification.

(a) Beginning June 1, 2018, only certified composite wood products, whether in the form of panels or incorporated into component parts or finished goods, are permitted to be sold, supplied, offered for sale, or manufactured (including imported) in the United States, unless the product is specifically exempted by this part.

* * * * *

(c) * * *

(1) * * *

(vii) Correlation data and linear regression equation (or, under the threshold approach, the correlation data and the upper limit); and

* * * * *

(2) * * *

(v) Correlation data and linear regression equation (or, under the threshold approach, the correlation data and the upper limit); and

* * * * *

■ 8. In § 770.17, revise paragraph (a)(4) to read as follows:

§ 770.17 No-added formaldehyde based resin.

(a) * * *

(4) Three months of routine quality control tests under § 770.20, including a showing of correlation in accordance with § 770.20(d)(2), totaling not less than thirteen quality control tests.

* * * * *

■ 9. In § 770.18, revise paragraph (a)(4) to read as follows:

§ 770.18 Ultra low-emitting formaldehyde based resins.

(a) * * *

(4) Six months of routine quality control tests under § 770.20, including a showing of correlation in accordance with § 770.20(d)(2), totaling not less than twenty-six quality control tests.

* * * * *

■ 10. In § 770.20:

■ a. Add paragraph (c)(2)(iv);

■ b. Revise paragraphs (d) and (d)(1);

■ c. Add paragraphs (d)(1)(iv) and (d)(1)(iv)(A) through (C);

■ d. Revise paragraphs (d)(2) introductory text and (d)(2)(i); and

■ e. Add paragraphs (d)(2)(i)(A) and (B).

The additions and revisions read as follows:

§ 770.20 Testing requirements.

* * * * *

(c) * * *

(2) * * *

(iv) Test results may represent a single chamber value or, the average value of testing nine specimens representing evenly distributed portions of an entire panel. The nine specimens must be tested in groups of three specimens, resulting in three test values, which must be averaged to represent one data point for the panel those specimens represent.

* * * * *

(d) *Equivalence or correlation.* Equivalence between ASTM E1333–14 (incorporated by reference, see § 770.99) and ASTM D6007–14 (incorporated by reference, see § 770.99) must be demonstrated by EPA TSCA Title VI TPCs at least once each year or whenever there is a significant change in equipment, procedure, or the qualifications of testing personnel, or reason to believe that the equivalence is no longer valid. Equivalence may be demonstrated between several similar model or size and construction ASTM E1333–14 (incorporated by reference, see § 770.99) and ASTM D6007–14 (incorporated by reference, see § 770.99) apparatuses located in the same EPA TSCA Title VI TPC laboratory. Once

equivalence has been established for three consecutive years, equivalence must be demonstrated every two years or whenever there is a significant change in equipment, procedure, or the qualifications of testing personnel. Correlation between ASTM E1333–14 (incorporated by reference, see § 770.99) or, upon a showing of equivalence in accordance with paragraph (d) of this section, ASTM D6007–14 (incorporated by reference, see § 770.99) and any other test method used for quality control testing must be demonstrated by EPA TSCA Title VI TPCs or panel producers, respectively, before the certification of composite wood products, and then whenever there is a significant change in equipment, procedure, the qualifications of testing personnel, or reason to believe that the correlation is no longer valid. Correlation may be established between several similar model or size and construction mill quality control test methods defined in § 770.20(b)(1) located at any one physical mill quality control testing laboratory to the EPA TSCA Title VI TPC's laboratory's ASTM E1333–14 (incorporated by reference, see § 770.99) and/or ASTM D6007–14 (incorporated by reference, see § 770.99) apparatus. If the TPC laboratory's ASTM E1333–14 or equivalent ASTM D6007–14 test chamber is used for panel producer quality control testing, no correlation as determined in § 770.20(d)(2) would be required.

(1) *Equivalence between ASTM E1333–14 and ASTM D6007–14 when used by the TPC for quarterly testing.* Equivalence must be demonstrated for at least five comparison sample sets in each range tested by the TPC, which compare the results of the two methods. Equivalence must be demonstrated for any ranges listed in § 770.20(d)(1)(iv) that represent the formaldehyde emissions of composite wood products tested by the TPC.

* * * * *

(iv) *Equivalence Ranges.* EPA TSCA Title VI TPCs must demonstrate equivalence in at least two of the three formaldehyde emission ranges listed in (d)(1)(iv)(A) through (C) of this section unless the EPA TSCA Title VI TPC will only certify products in one range. If the EPA TSCA Title VI TPC will only certify products in one range, the EPA TSCA Title VI TPC may demonstrate equivalence in only that one range and would then be restricted to only certifying composite wood products in that range. Equivalence in one range must be demonstrated for at least five comparison sample sets in that range which compare the two methods.

(A) Lower Range: Less than, or equal to 0.05 ppm.

(B) Intermediate Range: Greater than 0.05 ppm to less than or equal to 0.15 ppm.

(C) Upper Range: Greater than 0.15 to 0.25 ppm.

(2) *Correlation between ASTM E–1333–14 (incorporated by reference, see § 770.99), or equivalent ASTM D6007–14 (incorporated by reference, see § 770.99), and any quality control test method.* Correlation must be demonstrated by establishing an acceptable correlation coefficient (''r'' value) or following the threshold approach at § 770.20(d)(2)(i)(B).

(i) *Correlation.* The correlation must be based on a minimum sample size of five data pairs and a simple linear regression (unless the threshold approach at § 770.20(d)(2)(i)(B) is used) where the dependent variable (Y-axis) is the quality control test value and the independent variable (X-axis) is the ASTM E1333–14 (incorporated by reference, see § 770.99) test value or, upon a showing of equivalence in accordance with paragraph (d) of this section, the equivalent ASTM D6007–14 (incorporated by reference, see § 770.99) test value. Either composite wood products or formaldehyde emissions reference materials can be used to establish the correlation.

(A) *Cluster Approach.* A panel producer may work with its EPA TSCA Title VI TPC to develop a correlation and linear regression between the TPC's ASTM E1333–14 (incorporated by reference, see § 770.99) or equivalent ASTM D6007–14 (incorporated by reference, see § 770.99) test method and the panel producer's quality control method under § 770.20(b). In the event of clustered test results, a panel producer may fit a line through a point near the origin (the intersection of the X and Y axes) and the average value of the clustered data pairs. The point near the origin should represent the value for the EPA TSCA Title VI TPC's ASTM E1333–14 (incorporated by reference, see § 770.99) or equivalent ASTM D6007–14 (incorporated by reference, see § 770.99) test method and the panel producer's quality control method under § 770.20(b) when each testing apparatus is empty or when a very low emitting sample is tested. The average value of the clustered data pairs represents the average of a minimum of five data pairs that compare the test results of the EPA TSCA Title VI TPC's ASTM E1333–14 (incorporated by reference, see § 770.99) or equivalent ASTM D6007–14 (incorporated by reference, see § 770.99) test method with the panel producer's quality control method under § 770.20(b). The line between the point near the origin and the average value of the cluster provides the linear regression. This line may be used by the panel producer and TPC to develop a quality control limit for the product.

(B) *Threshold Approach.* As an alternative to the linear regression and cluster approaches, a panel producer may use the average value of the clustered data pairs from the EPA TSCA Title VI TPC's ASTM E1333–14 (incorporated by reference, see § 770.99) or equivalent ASTM D6007–14 (incorporated by reference, see § 770.99) test method and the panel producer's quality control method under § 770.20(b) as the quality control limit for the product. In this approach, no linear regression line is established. The average value would be assigned as the upper limit for production of the subject composite wood product, providing a margin of safety relative to the maximum value of the data cluster. This value, established as the quality control limit, must be below the applicable emission standard.

* * * * *

■ 11. In § 770.22, revise paragraph (c)(2)(i) and add paragraph (f)(1) to read as follows:

§ 770.22 Non-complying lots.

* * * * *

(c) * * *

(2) * * *

(i) At least one test panel must be randomly selected so that it is representative of the entire non-complying lot and is not the top or bottom panel of a bundle. Panel sampling shall be conducted according to the quarterly testing procedure at § 770.20(c)(2)(iv). The panel may be selected from properly stored samples set aside by the panel producer for retest in the event of a failure.

* * * * *

(f) * * *

(1) If a fabricator, importer, distributor, or retailer is notified that they have been supplied a non-complying lot after those composite wood products have been fabricated into component parts or finished goods, the notification requirement at paragraph (d)(1) of this section does not apply.

■ 12. In § 770.30, revise paragraphs (b) introductory text and (c) to read as follows:

§ 770.30 Importers, fabricators, distributors, and retailers.

* * * * *

(b) Importers must demonstrate that they have taken reasonable precautions

by maintaining, for three years, bills of lading, invoices, or comparable documents that include a written statement from the supplier that the composite wood products, component parts, or finished goods are TSCA Title VI compliant or were produced before June 1, 2018 and by ensuring the following records are made available to EPA within 30 calendar days of request:

* * * * *

(c) Fabricators, distributors, and retailers must demonstrate that they have taken reasonable precautions by obtaining bills of lading, invoices, or comparable documents that include a written statement from the supplier that the composite wood products, component parts, or finished goods are TSCA Title VI compliant or that the composite wood products were produced before June 1, 2018.

* * * * *

■ 13. In § 770.45, revise paragraph (a) introductory text and add paragraph (f) to read as follows:

§ 770.45 Labeling.

(a) Panels or bundles of panels that are imported, sold, supplied, or offered for sale in the United States must be labeled with the panel producer's name, the lot number, the number of the EPA TSCA Title VI TPC, and a statement that the products are TSCA Title VI certified (or, for products exempt from certain testing and certification pursuant to §§ 770.17 or 770.18, a statement that the products are TSCA Title VI compliant). If a composite wood panel is not individually labeled, the panel producer, importer, distributor, fabricator, or retailer must have a method (*e.g.,* color-coded edge marking) sufficient to identify the supplier of the panel and linking the information on the label to the products. This information must be made available to potential customers upon request. The label may be applied as a stamp, tag, or sticker.

* * * * *

(f) All panels (or bundles of panels) and finished goods (or boxes or bundles containing finished goods) must be properly labeled pursuant to paragraphs (a), (b), and (c) of this section before being imported into the United States, except as provided in paragraph (e) of this section.

■ 14. In § 770.99, revise paragraphs (e)(1) and (3) to read as follows:

§ 770.99 Incorporation by reference.

* * * * *

(e) * * *

(1) ISO/IEC 17011:2017(E) Conformity assessments—requirements for accreditation bodies accrediting conformity assessments bodies (Second Edition), November 2017.

* * * * *

(3) ISO/IEC 17025:2017(E) General requirements for the competence of testing and calibration laboratories (Third Edition), November 2017.

* * * * *

[FR Doc. 2018–23592 Filed 10–31–18; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 16 and 52

[FAR Case 2017–020; Docket No. 2017–0020, Sequence No. 1]

RIN 9000–AN58

Federal Acquisition Regulation: Ombudsman for Indefinite Delivery Contracts

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Proposed rule.

SUMMARY: DoD, GSA, and NASA are proposing to amend the Federal Acquisition Regulation (FAR) to implement a new clause for use in multiple-award indefinite-delivery, indefinite–quantity contracts that provides information on the task- and delivery-order ombudsman.

DATES: Interested parties should submit comments to the Regulatory Secretariat Division at one of the addresses shown below on or before December 31, 2018 to be considered in the formulation of a final rule.

ADDRESSES: Submit comments in response to FAR Case 2017–020 by any of the following methods:

• *Regulations.gov: http://www.regulations.gov.*

Submit comments via the Federal eRulemaking portal by entering ''FAR Case 2017–020'' under the heading ''Enter Keyword or ID'' and selecting ''Search.'' Select the link ''Comment Now'' that corresponds with ''FAR Case 2017–020.'' Follow the instructions provided on the screen. Please include your name, company name (if any), and ''FAR Case 2017–020'' on your attached document.

• *Mail:* General Services Administration, Regulatory-Secretariat Division (MVCB), ATTN: Lois Mandell, 1800 F Street NW, 2nd floor, Washington, DC 20405.

Instructions: Please submit comments only and cite ''FAR case 2017–020'' in all correspondence related to this case. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. 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: For clarification of content, contact Mr. Michael O. Jackson, Procurement Analyst, at 202–208–4949. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755. Please cite ''FAR Case 2017–020.''

SUPPLEMENTARY INFORMATION:

I. Background

DoD, GSA, and NASA are proposing to revise the FAR to implement a new clause that provides the agency task- and delivery-order ombudsman's responsibilities and contact information for use in multiple-award indefinite-delivery, indefinite-quantity (IDIQ) contracts. 10 U.S.C. 2304c and 41 U.S.C. 4106 require agencies to appoint or designate a task- and delivery-order ombudsman who is responsible for reviewing complaints from contractors and ensuring that all of the contractors are afforded a fair opportunity to be considered for the award of an order, consistent with the procedures in the contract.

To help implement the statutory requirement, FAR 16.504(a)(4)(v) requires the name, address, telephone number, facsimile number, and email address of the agency's task- and delivery-order ombudsman be included in IDIQ solicitations, if multiple awards may result from the solicitation, and multiple-award IDIQ contracts. As a result of the requirement at FAR 16.504, several agencies created an agency-level contract clause that provides this information to contractors. This rule provides a standardized way to provide the necessary information to contractors with a single contract clause for use by all agencies.

II. Discussion and Analysis

This rule proposes to amend the FAR, as follows:

• FAR part 16 is revised to add a prescription that requires the use of the

new clause in solicitations and contracts when a multiple-award, IDIQ contract is contemplated.

- FAR part 52 is revised to add a new clause at FAR 52.216–XX, Task-Order and Delivery-Order Ombudsman, that provides contractors with contact information (as a fill-in) for the agency ombudsman, explains the responsibilities of the ombudsman, and explains that contacting the ombudsman does not alter the timelines for other processes in the FAR.
- An Alternate I clause is added to the main clause for contracts used by multiple agencies. The Alternate I clause explains that for contracts used by multiple agencies, complaints from contractors concerning orders placed under multi-agency contracts are primarily reviewed by the task- and delivery-order ombudsman for the ordering agency and provides the offeror with the contact information for the ordering agency's ombudsman.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT) and for Commercial Items, Including Commercially Available Off-the-Shelf (COTS) Items

This rule proposes to create a new FAR clause 52.216–XX, Task-Order and Delivery-Order Ombudsman. The objective of the rule is to implement a single clause available for use by all agencies when awarding multiple-award IDIQ contracts that provides contractors with the requisite information for the agency task- and delivery-order ombudsman.

DoD, GSA, and NASA plan to apply this clause to solicitations and contracts for the acquisition of commercial items, including COTS items, as defined at FAR 2.101. This rule does not impose any burden on contractors. Rather, this rule provides contractors with information on the responsibilities of and how to contact the ombudsman. Not applying this guidance to contracts for the acquisition of commercial items, including COTS items, could prevent some contractors from receiving the requisite information needed to address an issue with an agency's task- and delivery-order ombudsman. Consequently, DoD, GSA, and NASA plan to apply the rule to contracts for the acquisition of commercial items, including COTS items.

The rule is not likely to apply to contracts at or below the SAT, since the value of multiple-award IDIQ contracts are usually above the SAT.

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under Section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

V. Executive Order 13771

This rule is not subject to E.O. 13771, because this rule is not a significant regulatory action under E.O. 12866.

VI. Regulatory Flexibility Act

DoD, GSA, and NASA do not expect this rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act 5 U.S.C. 601 *et seq.* However, an Initial Regulatory Flexibility Analysis (IRFA) has been performed and is summarized as follows:

The Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA) are proposing to revise the Federal Acquisition Regulation (FAR) to implement a new clause that provides the agency task- and delivery-order ombudsman's responsibilities and contact information for use in multiple-award indefinite-delivery, indefinite-quantity (IDIQ) contracts. 10 U.S.C. 2304c and 41 U.S.C. 4106 require agencies to appoint or designate a task- and delivery-order ombudsman who is responsible for reviewing complaints from contractors and ensuring that all of the contractors are afforded a fair opportunity to be considered for the award of an order, consistent with the procedures in the contract.

To help implement the statutory requirement, FAR 16.504(a)(4)(v) requires the name, address, telephone number, facsimile number, and email address of the agency's task- and delivery-order ombudsman be included in IDIQ solicitations and contracts, if multiple awards may result from the solicitation. As a result of the requirement at FAR 16.504, several agencies created an agency-level contract clause that provides this information to contractors. This rule provides a standardized way to provide the necessary information to contractors with a single contract clause for use by all agencies.

The objective of this proposed rule is to implement a single clause that provides contractors with the requisite information for the agency task- and delivery-order ombudsman and is available for use by all agencies when awarding a multiple-award IDIQ contract.

DoD, GSA, and NASA do not expect this rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* According to data from the Federal Procurement Data System, there were 6,207 new multiple-award contracts awarded in fiscal year 2017. Of the 6,207 new awards, 4,477 (72 percent) of these actions were awarded to 3,873 unique small business entities. The proposed rule applies to all entities who do business with the Federal Government and is not expected to have a significant impact on these entities, regardless of business size.

This proposed rule does not include any new reporting, recordkeeping, or other compliance requirements.

The proposed rule does not duplicate, overlap, or conflict with any other Federal rules. There are no known significant alternative approaches to the proposed rule that would meet the proposed objectives.

The Regulatory Secretariat Division has submitted a copy of the IRFA to the Chief Counsel for Advocacy of the Small Business Administration. A copy of the IRFA may be obtained from the Regulatory Secretariat Division. DoD, GSA and NASA invite comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DoD, GSA, and NASA will also consider comments from small entities concerning the existing regulations in subparts affected by this rule consistent with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (FAR Case 2017–020) in correspondence.

VII. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 16 and 52

Government procurement.

Dated: October 29, 2018.

William F. Clark,

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

Therefore, DoD, GSA, and NASA are proposing to amend 48 CFR parts 16 and 52 as set forth below:

■ 1. The authority citation for 48 CFR parts 16 and 52 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 51 U.S.C. 20113.

PART 16—TYPES OF CONTRACTS

16.504 [Amended]

■ 2. Amend section 16.504 by removing paragraph (a)(4)(v) and redesignating paragraphs (a)(4)(vi) and (a)(4)(vii) as paragraphs (a)(4)(v) and (a)(4)(vi), respectively.

■ 3. Amend section 16.506 by adding paragraph (j) to read as follows.

16.506 Solicitation provisions and contract clauses.

* * * * *

(j) Insert the clause at 52.216–XX, Task-Order and Delivery-Order Ombudsman, in solicitations and contracts when a multiple-award, indefinite-delivery, indefinite-quantity contract is contemplated. Use the clause with its Alternate I when the contract will be available for use by multiple agencies (*e.g.,* Governmentwide acquisition contracts or multi-agency contracts). When placing orders under a contract available for use by multiple agencies, the ordering agency's contracting officer shall complete paragraph (d)(2) and include Alternate I in the solicitation and any resulting order.

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 4. Add section 52.216–XX to read as follows:

52.216–XX Task-Order and Delivery-Order Ombudsman.

As prescribed in 16.506(j), use the following clause:

Task-Order and Delivery-Order Ombudsman (Date)

(a) In accordance with 41 U.S.C. 4106(g), the Agency has designated the following task-order and delivery-order Ombudsman for this contract. The Ombudsman must review complaints from the Contractor concerning all task- and delivery-order actions for this contract and ensure the Contractor is afforded a fair opportunity for consideration in the award of task- or delivery-orders, consistent with the procedures in the contract.

(*Contracting Officer to insert name, address, telephone number, and email address for the Agency Ombudsman or provide the URL address where this information may be found.*)

(b) Before consulting with the Ombudsman, the Contractor is encouraged to first address complaints with the Contracting Officer for resolution. When requested, the Ombudsman may keep the identity of the concerned party or entity confidential, unless prohibited by law or agency procedure.

(c) Consulting an ombudsman does not alter or postpone the timeline for any other process (*e.g.,* protests).

(End of clause)

Alternate I. As prescribed in 16.506(j), add the following paragraph (d) to the basic clause.

(d) *Contracts used by multiple agencies.*

(1) This is a contract that is used by multiple agencies. Complaints from Contractors concerning orders placed under contracts used by multiple agencies are primarily reviewed by the task-order and delivery-order Ombudsman for the ordering agency.

(2) The ordering agency has designated the following task-order and delivery-order Ombudsman for this order:

(*The ordering agency's contracting officer to insert the name, address, telephone number, and email address for the ordering agency's Ombudsman or provide the URL address where this information may be found.*)

(End of clause)

[FR Doc. 2018–23889 Filed 10–31–18; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No.: 180205127–8896–01]

RIN 0648–BH68

Fisheries of the Northeastern United States; Proposed Rule To Expand the Scallop Dredge Exemption Areas Under the Northeast Multispecies Fishery Management Plan

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to implement modifications to the regulations implementing the Northeast Multispecies Fishery Management Plan to allow vessels issued a limited access general category individual fishing quota sea scallop permit to fish for scallops with small dredges in an expanded area. In addition, NMFS also proposes to modify open area days-at-sea trip reporting procedures for limited access scallop vessels. This action is intended to provide consistency, flexibility, and potential economic benefit to the scallop fleet. This rule notifies the public of these proposed measures and solicits comments on the potential scallop fishery management changes.

DATES: Comments must be received by December 3, 2018.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2018–0118, by either of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2018-0118,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Regional Administrator, NMFS, Greater Atlantic Regional Fisheries Office, 55 Great Republic Drive, Gloucester, MA 01930. Mark the outside of the envelope, ''Comments on Scallop Dredge Exemption''.

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

Copies of the proposed rule to expand the scallop dredge exemption areas, and of the draft Environmental Assessment (EA) and preliminary Regulatory Impact Review (EA/RIR), are available from the Greater Atlantic Regional Fisheries Office, 55 Great Republic Drive, Gloucester, MA 01930. The EA/RIR is also accessible via the internet at: *www.greateratlantic.fisheries.noaa.gov.*

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this proposed rule may be submitted to the Greater Atlantic Regional Fisheries Office and by email to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Shannah Jaburek, Fishery Management Specialist, 978–282–8456.

SUPPLEMENTARY INFORMATION:

Background

Regulations implementing the Northeast (NE) Multispecies Fishery Management Plan (FMP) include a bycatch control measure for the Gulf of Maine (GOM), Georges Bank (GB), and Southern New England (SNE) Regulated Mesh Areas (RMA). A vessel may not

fish in these areas unless it is fishing under a multispecies or a scallop days-at-sea (DAS) allocation; is fishing with exempted gear; is fishing under the Handgear or Party/Charter permit restrictions; or is fishing in an exempted fishery (50 CFR 648.80(a)(3)(vi) and 50 CFR 648.80(b)(2)(vi)). The regulations found at 50 CFR 648.80(a)(8) give the Regional Administrator (RA) the authority to establish a new exempted fishery, or modify an existing exempted fishery, after consultation with the New England Fishery Management Council (Council), provided the bycatch of groundfish species is, or can be reduced to, less than five percent by weight of the total catch and the exempted fishery will not jeopardize the fishing mortality objectives of the NE Multispecies FMP.

The limited access general category (LAGC) individual fishing quota (IFQ) fleet currently operates in four different exemption areas: GOM scallop dredge exemption area (SDEA); Great South Channel (GSC) SDEA; SNE SDEA; and the Mid-Atlantic Exemption Area (Figure 1). Recently, some members of the scallop industry requested that NMFS expand the GSC and GOM SDEAs to encompass all of GB and the GOM. As a result, at its meeting on June 20, 2017, the Council recommended that the RA use his authority to expand the GSC SDEA to encompass all of GB. The Council is considering an amendment to the Scallop FMP to develop comprehensive management measures for the GOM, and therefore, it did not recommend that we expand the GOM SDEA. This proposed rule proposes to adopt and implement the Council's recommendation.

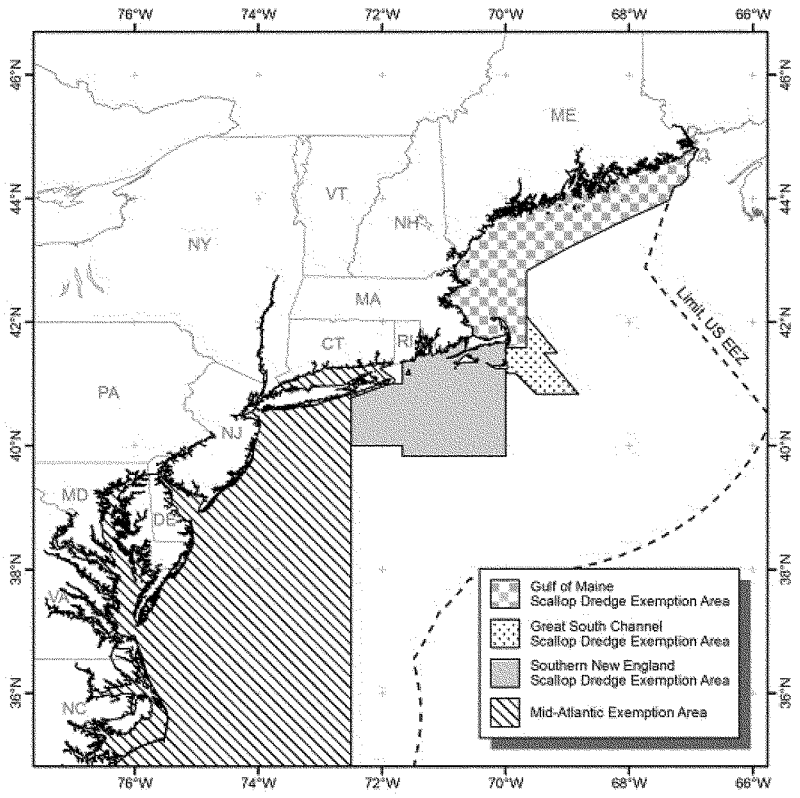
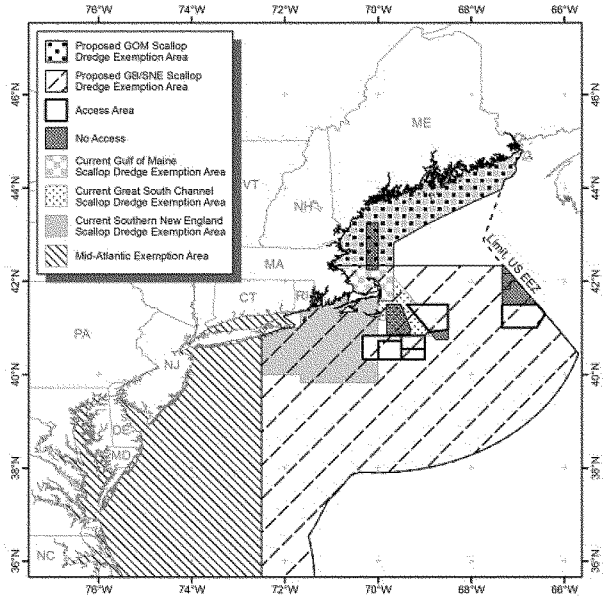


Figure 1. Map of Current Scallop Dredge Exemption Areas

The current exemptions in the SDEAs allow LAGC IFQ vessels to fish within the designated SDEA using dredge gear that is less than 10.5 feet wide. The exemptions allow these vessels to retain only scallops and up to 50 lb of monkfish tails per trip. One purpose of this action is to expand the area where these exemptions apply. Because the Mid-Atlantic Exemption Area is not subject to the same exemption conditions under the NE Multispecies FMP as the SDEAs, no changes are being proposed for the Mid-Atlantic Exemption area.

Based on consultations with the Council, the current SDEAs for the LAGC IFQ fleet would be expanded by eliminating the current GSC and SNE SDEAs designations and creating a new expanded exemption area called Georges Bank/Southern New England (GB/SNE) SDEA. The GB/SNE SDEA would encompass all fishing grounds south of 42°20′ N lat. and east of the Mid-Atlantic Exemption Area (Figure 2).

Figure 2. Map of Proposed Georges Bank/Southern New England Scallop Dredge Exemption Area



This new expanded exemption area would provide continuity for IFQ scallop fishing and achieve the following benefits:

- Include new areas that were originally part of the Nantucket Lightship Essential Fish Habitat Closure opened under the Omnibus Habitat Amendment 2 (OHA2) and are not currently accessible to the LAGC fleet; and
- Include an area off the coasts of Rhode Island, Connecticut, and New York that is not covered by current exemption areas, but where activity in the IFQ fishery has occurred.

The primary area that would open to LAGC fishing as a result of this action is the GB Broad Stock Area (BSA), which is made up of statistical reporting areas 522, 525, 542, 561, 562, and 543 (a map of the statistical reporting areas is available from the Regional Administrator upon request). Because LAGC dredge fishing is not currently permitted in these areas, we analyzed potential effect on groundfish catch by LAGC dredge fishing in the expansion area by looking at limited access and LAGC observed hauls in the Southern New England/Mid-Atlantic (SNE/MA) BSA and Statistical Area 521 from 2012 to 2016 (n=3,426). We determined that this information from these areas would be a valid way to estimate potential catch of groundfish in the newly expanded areas. In looking at this information, we excluded hauls that caught less than 40 lbs of scallop meats because these are not representative samples. Using the observer program information, we developed a ratio of groundfish discarded (*D*) to total catch (*K*) for both the limited access and LAGC fleets according to the following equation:

Percent Multispecies = [D/K] × 100

For this analysis, we summed the weights of groundfish caught on observed trips in the SNE/MA BSA and Statistical Area 521, and divided it into the total weight (n=374). Trips were aggregated across area, fishing year, and fleet. The ratios for both fleets were compared for differences using statistical analysis. We found that the limited access fleet had a bycatch rate of 0.52 percent of regulated species in the SNE BSA and the LAGC fleet had a bycatch rate of 0.53 percent of regulated species. There were no significant differences between bycatch rates of regulated species between the two fleets.

Limited access *D/K* ratios were then calculated from observed trips within the GB BSA. We used additional statistical analysis to determine the range of the likely rate of groundfish bycatch by the LAGC fleet in the GB BSA. We found that the limited access fleet had a bycatch rate of 1.07 percent of regulated species. Based on the combination of these two analyses, the expected range of regulated species bycatch for the LAGC fleet in the GB BSA would be between 0.99 percent and 1.25 percent. Further, an examination of rates within fishing years and individual areas revealed that there were no years or areas where the D/K rate exceeded 5 percent.

Based on data analysis perform by NMFS, the LAGC IFQ fishery is expected to meet the five-percent-or-less bycatch criteria for granting an exemption throughout the entirety of the GB and SNE RMAs. Further, because multispecies catch is controlled for the IFQ fleet by the sub-annual catch limits and there are accountability measures for yellowtail and windowpane flounder caught in the fishery, allowing the IFQ fleet to fish in the expanded area would not likely jeopardize fishing mortality limits for NE multispecies stocks.

In addition, this expanded exemption would help offset the effects on the closure to fishing implemented by the OHA2. The GSC Habitat Management Area (HMA) was created under the OHA2 within the existing GSC SDEA. The GSC HMA prohibits the use of all mobile fishing gear, including scallop dredge gear, year-round. Creating the new GB/SNE SDEA would provide additional fishing area, fishing opportunity, and greater flexibility and simplicity to the IFQ fleet.

This action also proposes to modify open area DAS trip reporting procedures by requiring that each limited access vessel submit a pre-landing notification form through its vessel monitoring system (VMS) unit prior to returning to port at the end of each DAS trip, including trips where no scallops were landed. At its June 13, 2018, meeting the Council requested that NMFS use its authority to require a VMS pre-landing notification on all limited access scallop trips to create reporting parity in the fishery with other limited access trips

and LAGC trips where this notification is required. NOAA's Office of Law Enforcement may use this information to assist in monitoring vessel activity and to improve compliance with the regulations.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), the Assistant Administrator has determined that this proposed rule is consistent with the NE Multispecies and Atlantic Sea Scallop FMPs, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

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

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. The proposed rule would expand the Great South Channel (GSC) Scallop Dredge Exemption Area (SDEA), as requested by the New England Fishery Management Council (Council). The existing exemption allows the limited access general category (LAGC) individual fishing quota (IFQ) scallop fleet to operate in the GSC SDEA with dredge gear.

The LAGC IFQ fleet currently operates in four different exemption areas: the Gulf of Maine (GOM), GSC, and Southern New England (SNE) SDEAs and the Mid-Atlantic Exemption Area. The current exemptions in the SDEAs allow LAGC IFQ vessels to fish within the designated SDEA using dredge gear that is less than 10.5 feet wide. The exemptions allow vessels to retain only scallops and up to 50 lb of monkfish tails per trip. The purpose this action is to expand the area where these exemptions apply. The Mid-Atlantic Exemption Area is not subject to the same exemption conditions under the Northeast (NE) Multispecies Fishery Management Plan (FMP) as the SDEAs, therefore the restrictions under the proposed action would not apply.

The proposed rule would:

- Remove the GSC and SNE SDEAs and exempt LAGC IFQ scallop fishing using dredge gear that is less than 10.5-ft wide south of 42°20′ N lat. and east of 72°30′ W long.;
- Provide continuity for IFQ scallop fishing south of 42°20′ N lat.;
- Include new areas that were originally part of the Nantucket Lightship Essential Fish Habitat Closure opened under the Omnibus Habitat Amendment 2 (OHA2) and are not currently accessible to the LAGC fleet; and
- Include an area off the coasts of Rhode Island, Connecticut, and New York that is not covered by current exemption areas, but where the IFQ fishery has fished.

The Regulatory Flexibility Act (RFA) requires Federal agencies to consider disproportionality and profitability to determine the significance of regulatory impacts. The RFA defines a small business in the shellfish fishery as a firm that is independently owned and operated with receipts of less than $11 million annually. Individually-permitted vessels may hold permits for several fisheries, harvesting species of fish that are regulated by several different fishery management plans, even beyond those impacted by the proposed action. Furthermore, multiple permitted vessels and/or permits may be owned by entities affiliated by stock ownership, common management, identity of interest, contractual relationships, or economic dependency. For the purposes of this analysis, ownership entities are defined as those entities with common ownership as listed on the permit application. Only permits with identical ownership are categorized as an ownership entity. For example, if five permits have the same seven persons listed as co-owners on their permit applications, those seven persons would form one ownership entity, that holds those five permits. If two of those seven owners also co-own additional vessels, that ownership arrangement would be considered a separate ownership entity for the purpose of this analysis.

On June 1 of each year, ownership entities are categorized as small. The current ownership dataset is based on the calendar year 2016 permits and contains average gross sales associated with those permits for calendar years 2014 through 2016. Matching the potentially impacted 2016 fishing year permits described above to calendar year 2016 ownership data results in 115 distinct ownership entities for the LAGC IFQ fleet. Less than three of the remaining LAGC IFQ entities are categorized as large entities.

NUMBER OF ACTIVE VESSELS AND BUSINESS ENTITIES WITH LAGC IFQ PERMITS

Year	Description	Small business
2014	No. of Entities	103
	No. of active LAGC IFQ Permits *	111
	Average Revenue per affiliation	$844,061
	Total Scallop revenue by vessels with IFQ permits	$24,269,674
	Total Affiliation Revenue	$86,938,240
2015	No. of Entities	101
	No. of active LAGC IFQ Permits*	108
	Average Revenue per affiliation	$864,696
	Total Scallop revenue by vessels with IFQ permits	$27,116,630
	Total Affiliation Revenue	$87,334,298
2016	No. of Entities	113
	No. of active LAGC IFQ Permits *	120
	Average Revenue per affiliation	$887,384
	Total Scallop revenue by vessels with IFQ permits	$35,629,220
	Total Affiliation Revenue	$100,274,409

* Number of permits refer only to LAGC IFQ permits. Affiliations could include several vessels with permits other than scallop.

The implementation of this action will expand the fishing area for all federal IFQ permit holders. Therefore, the small entities to which this action applies includes the majority of IFQ permit holders. NMFS does not expect the proposed action to have a substantial or disproportional negative impact on small businesses. NMFS

expects the profits of regulated small businesses identified in this analysis to be positive relative to the no action alternative. If approved and implemented, this action would provide greater operational flexibility for permit holders than current SDEA regulations.

Since there are cost savings resulting from this proposed rule, the impact on small entities would be a positive one. Permit holders would be able to maximize the profits of each fishing trip by having additional fishing grounds to choose from. Cost savings would be determined by individual permit holders based on the fuel cost variables associated with fishing trips. These costs would include the fuel needed to transit to the fishing grounds versus the fuel needed for fishing operations. If this rule is approved and implemented then individual permit holders would be able prioritize one cost over the other in order to maximize profits. For limited access vessels, the costs associated with the new requirement to send in a pre-landing notification report for open area trips is expected to be less than five dollars per fishing year and considered to be minimal in nature. Therefore, this rule will not have a significant economic impact on a substantial number of small entities. As a result, an Initial Regulatory Flexibility Analysis is not required and none has been prepared.

The proposed action contains a collection-of-information requirement subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA). The requirements will be submitted to OMB for approval under the NMFS Greater Atlantic Region Scallop Report Family of Forms (OMB Control No. 0648–0491).

Under the proposed action, all 347 limited access scallop vessels would be required to submit a pre-landing notification form for each DAS trip through their VMS units. This information collection is intended to improve DAS trip monitoring, as well as create reporting consistency for all scallop trips.

The pre-landing notification would include the following information: Operator's permit number; amount of scallop meats to be landed; the estimated time of arrival; the landing port and state where the scallops will be offloaded; and the vessel trip report (VTR) serial number recorded from that trip's VTR.

The burden estimates for these new requirements apply to all limited access scallop vessels. In a given fishing year, NMFS estimates that for DAS reporting, each of the 313 full-time limited access scallop vessels would submit a pre-landing report 3 times (939 responses) and each of the 34 part-time limited access vessels would submit a pre-landing report up to 2 times (68 responses), for a total of 1,007 responses. Public reporting burden for submitting this pre-landing notification form is estimated to average 5 minutes per response with an associated cost of $1.25, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Therefore, 1,007 responses would impose total compliance costs of $1,259.

Public comment is sought regarding: Whether this 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 burden estimate; 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, including through the use of automated collection techniques or other forms of information technology. Send comments on these or any other aspects of the collection of information to the Regional Administrator (See **ADDRESSES** above), and email to *OIRA_Submission@omb.eop.gov,* or fax to (202) 395–5806.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number. All currently approved NOAA collections of information may be viewed at: *http://www.cio.noaa.gov/services_programs/prasubs.html.*

This action contains no other compliance costs.

Federal Rules Which May Duplicate, Overlap or Conflict With This Proposed Rule

The proposed regulations do not create overlapping regulations with any state regulations or other Federal laws.

List of Subjects 50 CFR Part 648

Fisheries, Fishing, Recordkeeping and reporting requirements.

Dated: October 25, 2018.

Samuel D. Rauch III,

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

For the reasons set out in the preamble, 50 CFR part 648 is proposed to be amended as follows:

PART 648—FISHERIES OF THE NORTHEAST UNITED STATES

Subpart A—General Provisions

■ 1. The authority citation for part 648 continues to read as follows:

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

■ 2. In § 648.10, revise paragraph (f)(4)(iii) to read as follows:

§ 648.10 VMS and DAS requirements for vessel owners/operators.

* * * * *

(f) * * *

(4) * * *

(iii) *Scallop Pre-Landing Notification Form for limited access vessels fishing on scallop trips.* A limited access vessel on a declared sea scallop trip must report through VMS, using the Scallop Pre-Landing Notification Form, the amount of any scallops kept on each trip, including declared trips where no scallops were landed. The report must be submitted no less than 6 hours before arrival, or, if fishing ends less than 6 hours before arrival, immediately after fishing ends. If scallops will be landed, the report must include the vessel operator's permit number, the amount of scallop meats in pounds to be landed, the number of bushels of in-shell scallops to be landed, the estimated time of arrival, the landing port and state where the scallops will be offloaded, and the VTR serial number recorded from that trip's VTR (the same VTR serial number as reported to the dealer). If no scallops will be landed, a limited access vessel on a declared sea scallop trip must provide only the vessel's captain/operator's permit number, the VTR serial number recorded from that trip's VTR (the same VTR serial number as reported to the dealer), and confirmation that no scallops will be landed. A limited access scallop vessel may provide a corrected report. If the report is being submitted as a correction of a prior report, the information entered into the notification form will replace the data previously submitted in the prior report. Submitting a correction does not prevent NMFS from pursuing an enforcement action for any false reporting. A vessel may not offload its

catch from a Sea Scallop Access Area trip at more than one location per trip.

* * * * *

■ 3. In § 648.14, revise paragraph (k)(5)(i) to read as follows:

§ 648.14 Prohibitions.

* * * * *

(k) * * *

(5) * * *

(i) Violate any of the provisions of § 648.80, including paragraphs (a)(5), the Small-mesh Northern Shrimp Fishery Exemption Area; (a)(6), the Cultivator Shoal Whiting Fishery Exemption Area; (a)(9), Small-mesh Area 1/Small-mesh Area 2; (a)(10), the Nantucket Shoals Dogfish Fishery Exemption Area; (h)(3)(i), the GOM Scallop Dredge Exemption Area; (a)(12), the Nantucket Shoals Mussel and Sea Urchin Dredge Exemption Area; (a)(13), the GOM/GB Monkfish Gillnet Exemption Area; (a)(14), the GOM/GB Dogfish Gillnet Exemption Area; (a)(15), the Raised Footrope Trawl Exempted Whiting Fishery; (a)(16), the GOM Grate Raised Footrope Trawl Exempted Whiting Fishery; (h)(3)(ii), the Georges Bank/Southern New England Scallop Dredge Exemption Area; (a)(19), the Eastern and Western Cape Cod Spiny Dogfish Exemption Areas; (b)(3), exemptions (small mesh); (b)(5), the SNE Monkfish and Skate Trawl Exemption Area; (b)(6), the SNE Monkfish and Skate Gillnet Exemption Area; (b)(8), the SNE Mussel and Sea Urchin Dredge Exemption Area; (b)(9), the SNE Little Tunny Gillnet Exemption Area;(h)(3)(ii); or (b)(12), the SNE Skate Bait Trawl Exemption Area. Each violation of any provision in § 648.80 constitutes a separate violation.

* * * * *

Subpart D—Management Measures for the Atlantic Sea Scallop Fishery

■ 4. In § 648.51, revise paragraph (b)(1) to read as follows:

§ 648.51 Gear and crew restrictions

* * * * *

(b) * * *

(1) *Maximum dredge width.* The combined dredge width in use by or in possession on board such vessels shall not exceed 31 ft (9.4 m), measured at the widest point in the bail of the dredge, except as provided under paragraph (e) of this section, in § 648.59(g)(2), and the scallop dredge exemption areas specified in § 648.80(h). However, component parts may be on board the vessel such that they do not conform with the definition of ''dredge or dredge gear'' in § 648.2, *i.e.,* the metal ring bag and the mouth frame, or bail, of the dredge are not attached, and such that no more than one complete spare dredge could be made from these component's parts.

* * * * *

■ 5. In § 648.62, revise paragraph (a) to read as follows:

§ 648.62 Northern Gulf of Maine (NGOM) Management Program.

(a) The NGOM scallop management area is the area north of 42°20′ N. lat. and within the boundaries of the Gulf of Maine Scallop Dredge Exemption Area as specified in § 648.80(h)(3)(i). To fish for or possess scallops in the NGOM scallop management area, a vessel must have been issued a scallop permit as specified in § 648.4(a)(2).

* * * * *

Subpart F—Management Measures for the Northeast Multispecies Fishery

■ 6. In § 648.80,

■ a. Revise paragraphs (a)(3)(vi), (b)(2)(vi), (h)(1);

■ b. Remove and reserve paragraphs (a)(11), (a)(18), and (b)(11); and

■ c. Add new paragraph (h)(3), to read as follows:

§ 648.80 NE Multispecies regulated mesh areas and restrictions on gear and methods of fishing.

(a) * * *

(3) * * *

(vi) *Other restrictions and exemptions.* A vessel is prohibited from fishing in the GOM or GB Exemption Area as defined in paragraph (a)(17) of this section, except if fishing with exempted gear (as defined under this part) or under the exemptions specified in paragraphs (a)(5) through (7), (a)(9) through (a)(16) and (a)(18) through (a)(19), (d), (e), (h), and (i) of this section; or if fishing under a NE multispecies DAS; or if fishing on a sector trip; or if fishing under the Small Vessel or Handgear A permit specified in § 648.82(b)(5) and (6), respectively; or if fishing under a Handgear B permit specified in § 648.88(a); or if fishing under the scallop state waters exemptions specified in § 648.54 and paragraph (h)(3)(i)of this section; or if fishing under a scallop DAS or general category trip in accordance with paragraph (h) of this section; or if fishing pursuant to a NE multispecies open access Charter/Party or Handgear permit specified in § 648.88; or if fishing as a charter/party or private recreational vessel in compliance with § 648.89. Any gear used by a vessel in this area must be authorized under one of these exemptions. Any gear on a vessel that is not authorized under one of these exemptions must be stowed and not available for immediate use as defined in § 648.2

* * * * *

(b) * * *

(2) * * *

(vi) *Other restrictions and exemptions.* A vessel is prohibited from fishing in the SNE Exemption Area, as defined in paragraph (b)(10) of this section, except if fishing with exempted gear (as defined under this part) or under the exemptions specified in paragraphs (b)(3), (b)(5) through (9), (b)(12), (c), (e), (h), and (i) of this section; or if fishing under a NE multispecies DAS; or if fishing on a sector trip; or if fishing under the Small Vessel or Handgear A permit specified in § 648.82(b)(5) and (6), respectively; or if fishing under a Handgear B permit specified in § 648.88(a); or if fishing under a scallop state waters exemption specified in § 648.54; or if fishing under a scallop DAS or General Category scallop permit in accordance with paragraph (h) of this section; or if fishing pursuant to a NE multispecies open access Charter/Party or Handgear permit specified in § 648.88; or if fishing as a charter/party or private recreational vessel in compliance with the regulations specified in § 648.89. Any gear on a vessel, or used by a vessel, in this area must be authorized under one of these exemptions or must be stowed and not available for immediate use as defined in § 648.2.

* * * * *

(h) *Scallop vessels.* (1) Except as provided in paragraph (h)(2) and (3) of this section, a scallop vessel that possesses a limited access scallop permit and either a NE multispecies Combination vessel permit or a scallop/multispecies possession limit permit, and that is fishing under a scallop DAS allocated under § 648.53, may possess and land up to 300 lb (136.1 kg) of regulated species per trip, provided that the amount of regulated species on board the vessel does not exceed the trip limits specified in § 648.86, and provided the vessel has at least one standard tote on board, unless otherwise restricted by § 648.86(a)(2).

* * * * *

(3) *Scallop dredge exemption areas for general category scallop permits*

(i) *GOM Scallop Dredge Exemption Area.* Unless otherwise prohibited in § 648.81, § 648.370, or § 648.371, vessels with a limited access scallop permit that have declared out of the DAS program as specified in § 648.10, or that have used up their DAS allocations, and vessels issued a General Category scallop permit, may fish in the GOM Regulated Mesh Area specified in

paragraph (a)(1) of this section, when not under a NE multispecies DAS, providing the vessel fishes in the GOM Scallop Dredge Exemption Area and complies with the requirements specified in paragraph (h)(3)(iii) of this section. The GOM Scallop Dredge Fishery Exemption Area is bounded on the west and north by the coastlines of Massachusetts, New Hampshire, and Maine, bounded on the east by the U.S.-Canada Maritime Boundary, and bounded on the south by straight lines connecting the following points in the order stated:

GOM Scallop Dredge Exemption Area

Point	N lat.	W long.
GOM1	43°58′	(1)
GOM2	43°58′	67°22′
GOM3	43°41′	68°00′
GOM4	43°12′	69°00′
GOM5	42°49.5′	69°40′
GOM6	42°20′	69°40′
GOM7	42°20′	(2)

[1] The intersection of 43°58′ N lat. and the U.S.-Canada Maritime boundary.

[2] The intersection of 42°20′ N lat. and the coastline of Massachusetts.

(ii) *Georges Bank/Southern New England Scallop Dredge Exemption Area.* Unless otherwise prohibited in § 648.81, § 648.370, or § 648.371, vessels issued a LAGC scallop permit, including limited access scallop permits that have used up their DAS allocations, may fish in the Georges Bank/Southern New England Scallop Dredge Exemption Area, as defined under paragraph (h)(3)(ii)(A) of this section, when not under a NE multispecies or scallop DAS or on a sector trip, provided the vessel complies with the requirements specified in paragraph (h)(3)(iii) of this section and applicable scallop regulations in subpart D of this part.

(A) *Area Definition.* The Georges Bank/Southern New England dredge exemption area is bounded on the north by 42°20′ N lat.; bounded on the east by the U.S.-Canada Maritime boundary and the outer limit of the US EEZ; bounded on the west by 72°30′ W long. from the outer limit of the US EEZ to the south-facing coastline of Long Island; and bounded on the northwest by the following points, connected as noted in the order listed:

GB/SNE Scallop Dredge Exemption Area

Point	N lat.	W long.	Note
1	The south-facing coastline of Long Island.	72°30′ W	From Point 1 to Point 2 following the coastline of Long Island.
2	41°00′ N	The southeast-facing coast of Long Island.	From Point 2 to Point 3 following a straight line.
3	41°00′ N	The 3 nautical mile line, approximately 71°51.841′ W long.	From Point 3 to Point 4 following the Submerged Lands Act (3 nautical mile) line.
4	41°4.25′ N	The 3 nautical mile line, approximately 71°47.384′ W long.	From Point 4 to Point 5 following a straight line.
5	41°15′ N	72°2.25′ W	Point 5 represents Race Point, Fishers Island, NY. From Point 5 to Point 6 following a straight line northeasterly through Fishers Island, NY.
6	41°18.2′ N	71°51.5′ W	Point 6 represents Watch Hill, RI. From Point 6 to Point 7 following the coastlines of Rhode Island and Massachusetts.
7	42°20′ N	The coastline of Massachusetts.	

(B) [Reserved]

(iii) *Requirements.* (A) A vessel fishing in the Scallop Dredge Fishery Exemption Areas specified in paragraphs (h)(3)(i) and (ii) of this section may not fish for, possess on board, or land any species of fish other than Atlantic sea scallops and up to 50 lb (23 kg) tail weight or 166 lb (75 kg) whole weight of monkfish per trip.

(B) The combined dredge width in use by, or in possession on board, vessels fishing in the Scallop Dredge Fishery Exemption Areas may not exceed 10.5 ft (3.2 m), measured at the widest point in the bail of the dredge.

(C) The exemption does not apply to the Cashes Ledge Closure Area or the Western GOM Area Closure specified in § 648.81(a)(3) and (4), respectively.

[FR Doc. 2018–23790 Filed 10–31–18; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 83, No. 212
Thursday, November 1, 2018

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2018–0059]

Secretary's Advisory Committee on Animal Health; Intent To Reestablish

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of intent.

SUMMARY: We are giving notice that the Secretary of Agriculture intends to reestablish the Secretary's Advisory Committee on Animal Health for a 2-year period. The Secretary has determined that the Committee is necessary and in the public interest.

FOR FURTHER INFORMATION CONTACT: Dr. Tyler McAlpin, Designated Federal Officer, VS, APHIS, 4700 River Road Unit 43, Riverdale, MD 20737, (301) 851–3458.

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act (FACA, 5 U.S.C. App.), notice is hereby given that the Secretary of Agriculture intends to reestablish the Secretary's Advisory Committee on Animal Health (the Committee) for 2 years from the filing date of the charter's reestablishment.

The Committee advises the Secretary on strategies, policies, and programs to prevent, control, or eradicate animal diseases. The Committee considers agricultural initiatives of national scope and significance and advises on matters of public health, conservation of national resources, stability of livestock economies, livestock disease management and traceability strategies, prioritizing animal health imperatives, and other related aspects of agriculture. The Committee Chairperson and Vice Chairperson are elected by the Committee from among its members.

Done in Washington, DC, on October 26, 2018.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2018–23836 Filed 10–31–18; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

Agency: U.S. Census Bureau.

Title: Quarterly Survey of Public Pensions.

OMB Control Number: 0607–0143.

Form Number(s): F–10.

Type of Request: Revision of a currently approved collection.

Number of Respondents: 100.

Average Hours per Response: 45 minutes.

Burden Hours: 300.

Needs and Uses: The Quarterly Survey of Public Pensions, provides a rich source of data on public retirement systems administered by state and local governments in the United States. Data have been collected since 1968. Over 3.7 trillion dollars in public pension assets in the financial markets are controlled by a small number of large retirement systems. The Quarterly Survey of Public Pensions is used to collect data on the assets, revenues and expenditures of the 100 largest systems.

This survey was initiated at the request of both the Council of Economic Advisers and the Federal Reserve Board. The most important information this survey provides is the quarterly change in composition of the securities holdings of the defined benefit public employee retirement systems component of the economy. The Federal Reserve Board uses these data to track the public sector portion of the Flow of Funds Accounts. Additionally, the data are used by a variety of government officials, academics, students and non-profit organizations to analyze trends in public employee retirement and the impact of retirement obligations on the fiscal well-being of state and local governments.

Currently, we are requesting approval to conduct the 2019, 2020 and 2021 Quarterly Survey of Public Pensions. Discussions with the Federal Reserve Board and data providers and literature review have revealed that there is little interest in the measurement of revenue and benefits on a quarterly basis. Many systems do not produce these data quarterly. Obtaining these data requires consultation with multiple offices and the finalization of these data often lag behind asset data. Additionally, there is burden on data providers to produce these data quarterly. Therefore, we are proposing a realignment of content. We request approval to modify the current questionnaire to focus on the asset base of public employee retirement systems and to remove questions pertaining to measurement of revenue and benefits from the quarterly program.

The survey will provide greater focus on the asset composition of the largest systems. These data are already produced for existing internal and external needs, and most closely align with the needs of the Federal Reserve Board. Additionally, the related Annual Survey of Public Pensions (0607–0585) will continue to provide a robust collection of revenue and benefit data on a fiscal year basis. These data items are in demand on an annual basis and are already created for internal and external purposes by most all systems as they are required items in Comprehensive Annual Financial Reports (CAFRs).

Summary tables of the information collected are released quarterly on the internet. Documentation and explanatory materials are also available on the internet site here: *https://www.census.gov/programs-surveys/qspp.html.*

Affected Public: State, local or Tribal government.

Frequency: Quarterly.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C., Sections 161 and 182.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this

notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Sheleen Dumas,

Departmental Lead PRA Officer, Office of the Chief Information Officer.

[FR Doc. 2018–23859 Filed 10–31–18; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

Agency: U.S. Census Bureau.

Title: Spatial, Address, and Imagery Data Program (SAID).

OMB Control Number: 0607–XXXX.

Form Number(s): N/A.

Type of Request: Regular submission.

Needs and Uses: The Spatial, Address, and Imagery Data (SAID) Program, formerly known as the Geographic Support System Partnership Program, is one of seven voluntary geographic partnership programs that collect data to update the U.S. Census Bureau's geographic database of addresses, streets, boundaries, and imagery known as the Master Address File/Topologically Integrated Geocoding and Referencing (MAF/TIGER) System.

The data within the MAF/TIGER System supports the Census Bureau's geographic framework for data collection, tabulation and dissemination. This framework enables the Census Bureau field personnel to navigate to the appropriate locations for data collection, and it enables the Census Bureau to accurately link demographic data from surveys and the decennial census to locations and areas, such as cities, school districts, and counties for data tabulation and dissemination.

The data collected in the SAID Program is also used to define geographic boundaries, including census blocks, and to place households and group quarters in a specific census block. The SAID Program follows the process below:

1. The Census Bureau invites participants, including tribal, state, county, and local governments; federal agencies; and other organizations each fiscal year.

2. Participants provide a current address data with associated location points and attributes, spatial data, and/or imagery that is no more than two years old.

3. Participants upload the requested data files to a Census Bureau Secure File Transfer Protocol site, per Census Bureau procedures, or provide a media from which the data can be acquired.

4. The Census Bureau updates the MAF/TIGER System with the address and street centerline data provided by the participants and uses the provided imagery for quality control and change detection.

5. The Census Bureau uses these updated addresses, streets, and imagery to support Census Bureau field operations, surveys, and data tabulation.

The SAID Program provides the Census Bureau with a continuous method to obtain current, accurate, and complete address, spatial, and imagery data. The SAID Program helps the Census Bureau maintain its geographic framework for data collection, tabulation, and dissemination between decennial censuses and to support ongoing programs, such as the American Community Survey and the Population Estimates Program. Over the past six years, the SAID Program, under the name of the Geographic Support System Partnership Program, has enabled the Census Bureau to update addresses and street centerlines across the country, with participation covering nearly 94 percent of the housing units in the nation. Moving forward, the SAID Program will continue to focus on acquiring addresses, street centerlines, and imagery in targeted areas. The Geographic Support System Partnership Program was previously included in the Geographic Partnership Program Generic Clearance (OMB Control Number 0607–0795).

Affected Public: Tribal, state, county, and local governments and organizations.

Calculation of total burden	Burden hours per contact	Estimated number of respondents	FY 2019 total burden	FY 2020 total burden	FY 2021 total burden	FY19–FY21 total burden
Contact with Local Governments	2	1,000	2,000	2,000	2,000	6,000
Acquisition of Local Data	10	500	5,000	5,000	5,000	15,000
Total Burden	12	.....	7,000	7,000	7,000	21,000

Estimated Total Annual Cost to Public: $0. (This is not the cost of respondents' time, but the indirect costs respondents may incur for such things as purchases of specialized software or hardware needed to report, or expenditures for accounting or records maintenance services required specifically by the collection.)

Frequency: Annual collection.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C. Sections 16, 141, and 193.

This information collection request may be viewed at www.reginfo.gov. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Sheleen Dumas,

Departmental Lead PRA Officer, Office of the Chief Information Officer.

[FR Doc. 2018–23860 Filed 10–31–18; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

International Trade Administration

Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Advance Notification of Sunset Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

Background

Every five years, pursuant to the Tariff Act of 1930, as amended (the Act), the Department of Commerce (Commerce) and the International Trade Commission automatically initiate and conduct reviews to determine whether revocation of a countervailing or

antidumping duty order or termination of an investigation suspended under section 704 or 734 of the Act would be likely to lead to continuation or recurrence of dumping or a countervailable subsidy (as the case may be) and of material injury.

Upcoming Sunset Reviews for December 2018

Pursuant to section 751(c) of the Act, the following Sunset Review is scheduled for initiation in December 2018 and will appear in that month's *Notice of Initiation of Five-Year Sunset Reviews* (Sunset Review).

	Department contact
Antidumping Duty Proceedings	
Steel Nails from China (A–570–909) (2nd Review)	Matthew Renkey, (202) 482–2312.

Countervailing Duty Proceedings

No Sunset Review of countervailing duty orders is scheduled for initiation in December 2018.

Suspended Investigations

No Sunset Review of suspended investigations is scheduled for initiation in December 2018.

Commerce's procedures for the conduct of Sunset Review are set forth in 19 CFR 351.218. The *Notice of Initiation of Five-Year (Sunset) Review* provides further information regarding what is required of all parties to participate in Sunset Review.

Pursuant to 19 CFR 351.103(c), Commerce will maintain and make available a service list for these proceedings. To facilitate the timely preparation of the service list(s), it is requested that those seeking recognition as interested parties to a proceeding contact Commerce in writing within 10 days of the publication of the Notice of Initiation.

Please note that if Commerce receives a Notice of Intent to Participate from a member of the domestic industry within 15 days of the date of initiation, the review will continue.

Thereafter, any interested party wishing to participate in the Sunset Review must provide substantive comments in response to the notice of initiation no later than 30 days after the date of initiation.

This notice is not required by statute but is published as a service to the international trading community.

Dated: October 19, 2018.

James Maeder,

Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations performing the duties of Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2018–23876 Filed 10–31–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

FOR FURTHER INFORMATION CONTACT: Brenda E. Brown, Office of AD/CVD Operations, Customs Liaison Unit, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, telephone: (202) 482–4735.

Background

Each year during the anniversary month of the publication of an antidumping or countervailing duty order, finding, or suspended investigation, an interested party, as defined in section 771(9) of the Tariff Act of 1930, as amended (the Act), may request, in accordance with 19 CFR 351.213, that the Department of Commerce (Commerce) conduct an administrative review of that antidumping or countervailing duty order, finding, or suspended investigation.

All deadlines for the submission of comments or actions by Commerce discussed below refer to the number of calendar days from the applicable starting date.

Respondent Selection

In the event Commerce limits the number of respondents for individual examination for administrative reviews initiated pursuant to requests made for the orders identified below, Commerce intends to select respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports during the period of review. We intend to release the CBP data under Administrative Protective Order (APO) to all parties having an APO within five days of publication of the initiation notice and to make our decision regarding respondent selection within 21 days of publication of the initiation **Federal Register** notice. Therefore, we encourage all parties interested in commenting on respondent selection to submit their APO applications on the date of publication of the initiation notice, or as soon thereafter as possible. Commerce invites comments regarding the CBP data and respondent selection within five days of placement of the CBP data on the record of the review.

In the event Commerce decides it is necessary to limit individual examination of respondents and conduct respondent selection under section 777A(c)(2) of the Act:

In general, Commerce finds that determinations concerning whether particular companies should be ''collapsed'' (*i.e.,* treated as a single entity for purposes of calculating antidumping duty rates) require a substantial amount of detailed information and analysis, which often require follow-up questions and analysis. Accordingly, Commerce will not conduct collapsing analyses at the respondent selection phase of a review and will not collapse companies at the respondent selection phase unless there has been a determination to collapse certain companies in a previous segment of this antidumping proceeding (*i.e.,* investigation, administrative review, new shipper review or changed circumstances review). For any company subject to a review, if Commerce determined, or continued to treat, that company as collapsed with others, Commerce will assume that such companies continue to operate in the same manner and will collapse them for respondent selection purposes. Otherwise, Commerce will not collapse companies for purposes of respondent selection. Parties are requested to (a) identify which companies subject to review previously were collapsed, and (b) provide a citation to the proceeding in which they were collapsed. Further, if companies are requested to complete

a Quantity and Value Questionnaire for purposes of respondent selection, in general each company must report volume and value data separately for itself. Parties should not include data for any other party, even if they believe they should be treated as a single entity with that other party. If a company was collapsed with another company or companies in the most recently completed segment of a proceeding where Commerce considered collapsing that entity, complete quantity and value data for that collapsed entity must be submitted.

Deadline for Withdrawal of Request for Administrative Review

Pursuant to 19 CFR 351.213(d)(1), a party that requests a review may withdraw that request within 90 days of the date of publication of the notice of initiation of the requested review. The regulation provides that Commerce may extend this time if it is reasonable to do so. Determinations by Commerce to extend the 90-day deadline will be made on a case-by-case basis.

Opportunity to Request a Review: Not later than the last day of October 2018,[1] interested parties may request administrative review of the following orders, findings, or suspended investigations, with anniversary dates in October for the following periods:

	Period of review
Antidumping Duty Proceedings	
BRAZIL: Circular Welded Non-Alloy Steel Pipe, A–351–809	11/1/17–10/31/18
INDIA: Welded Stainless Pressure Pipe, A–533–867	11/1/17–10/31/18
INDONESIA:	
Certain Coated Paper Suitable for High-Quality Print Graphics Using Sheet-Fed Presses, A–560–823	11/1/17–10/31/18
Monosodium Glutamate, A–560–826	11/1/17–10/31/18
MEXICO:	
Certain Circular Welded Non-Alloy Steel Pipe, A–201–805	11/1/17–10/31/18
Seamless Refined Copper Pipe and Tube, A–201–838	11/1/17–10/31/18
Steel Concrete Reinforcing Bar, A–201–844	11/1/17–10/31/18
REPUBLIC OF KOREA: Certain Circular Welded Non-Alloy Steel Pipe, A–580–809	11/1/17–10/31/18
TAIWAN:	
Certain Circular Welded Non-Alloy Steel Pipe, A–583–814	11/1/17–10/31/18
Certain Hot-Rolled Carbon Steel Flat Products, A–583–835	11/1/17–10/31/18
THAILAND: Certain Hot-Rolled Carbon Steel Flat Products, A–549–817	11/1/17–10/31/18
THE PEOPLE'S REPUBLIC OF CHINA:	
Certain Cut-To-Length Carbon Steel, A–570–849	11/1/17–10/31/18
Certain Hot-Rolled Carbon Steel Flat Products, A–570–865	11/1/17–10/31/18
Certain Coated Paper Suitable for High-Quality Print Graphics Using Sheet-Fed Presses, A–570–958	11/1/17–10/31/18
Diamond Sawblades and Parts Thereof, A–570–900	11/1/17–10/31/18
Fresh Garlic, A–570–831	11/1/17–10/31/18
Lightweight Thermal Paper, A–570–920	11/1/17–10/31/18
Monosodium Glutamate, A–570–992	11/1/17–10/31/18
Paper Clips, A–570–826	11/1/17–10/31/18
Polyethylene Terephthalate (Pet) Film, A–570–924	11/1/17–10/31/18
Pure Magnesium in Granular Form, A–570–864	11/1/17–10/31/18
Refined Brown Aluminum Oxide, A–570–882	11/1/17–10/31/18
Seamless Carbon and Alloy Steel Standard, Line, and Pressure Pipe, A–570–956	11/1/17–10/31/18
Seamless Refined Copper Pipe and Tube, A–570–964	11/1/17–10/31/18
UKRAINE: Certain Hot-Rolled Carbon Steel Flat Products, A–823–811	11/1/17–10/31/18
UNITED ARAB EMIRATES: Polyethylene Terephthalate (Pet) Film, A–520–803	11/1/17–10/31/18
Countervailing Duty Proceedings	
INDIA: Welded Stainless Pressure Pipe, C–533–868	1/1/17–12/31/17
INDONESIA: Certain Coated Paper Suitable for High-Quality Print Graphics Using Sheet-Fed Presses, C–560–824	1/1/17–12/31/17
THE PEOPLE'S REPUBLIC OF CHINA:	
Certain Coated Paper Suitable for High-Quality Print Graphics Using Sheet-Fed Presses, C–570–959	1/1/17–12/31/17
Chlorinated Isocyanurates, C–570–991	1/1/17–12/31/17
Lightweight Thermal Paper, C–570–921	1/1/17–12/31/17
Seamless Carbon and Alloy Steel Standard, Line, and Pressure Pipe, C–570–957	11/1/17–10/31/18
TURKEY: Steel Concrete Reinforcing Bar, C–489–819	1/1/17–12/31/17
Suspension Agreements	
UKRAINE: Certain Cut-To-Length Carbon Steel Plate, A–823–808	11/1/18–12/31/18

In accordance with 19 CFR 351.213(b), an interested party as defined by section 771(9) of the Act may request in writing that the Secretary conduct an administrative review. For both antidumping and countervailing duty reviews, the interested party must specify the individual producers or exporters covered by an antidumping finding or an antidumping or countervailing duty order or suspension agreement for which it is requesting a review. In addition, a domestic interested party or an interested party described in section 771(9)(B) of the Act must state why it desires the Secretary to review those particular producers or exporters. If the interested party intends for the Secretary to review sales of merchandise by an exporter (or a producer if that producer also exports merchandise from other suppliers) which was produced in more than one country of origin and each country of

[1] Or the next business day, if the deadline falls on a weekend, federal holiday or any other day when Commerce is closed.

origin is subject to a separate order, then the interested party must state specifically, on an order-by-order basis, which exporter(s) the request is intended to cover.

Note that, for any party Commerce was unable to locate in prior segments, Commerce will not accept a request for an administrative review of that party absent new information as to the party's location. Moreover, if the interested party who files a request for review is unable to locate the producer or exporter for which it requested the review, the interested party must provide an explanation of the attempts it made to locate the producer or exporter at the same time it files its request for review, in order for the Secretary to determine if the interested party's attempts were reasonable, pursuant to 19 CFR 351.303(f)(3)(ii).

As explained in *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003), and *Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011), Commerce clarified its practice with respect to the collection of final antidumping duties on imports of merchandise where intermediate firms are involved. The public should be aware of this clarification in determining whether to request an administrative review of merchandise subject to antidumping findings and orders.[2]

Commerce no longer considers the non-market economy (NME) entity as an exporter conditionally subject to an antidumping duty administrative reviews.[3] Accordingly, the NME entity will not be under review unless Commerce specifically receives a request for, or self-initiates, a review of the NME entity.[4] In administrative reviews of antidumping duty orders on merchandise from NME countries where a review of the NME entity has not been initiated, but where an individual exporter for which a review was initiated does not qualify for a separate rate, Commerce will issue a final decision indicating that the company in question is part of the NME entity. However, in that situation, because no review of the NME entity was conducted, the NME entity's entries were not subject to the review and the rate for the NME entity is not subject to change as a result of that review (although the rate for the individual exporter may change as a function of the finding that the exporter is part of the NME entity). Following initiation of an antidumping administrative review when there is no review requested of the NME entity, Commerce will instruct CBP to liquidate entries for all exporters not named in the initiation notice, including those that were suspended at the NME entity rate.

All requests must be filed electronically in Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS) on Enforcement and Compliance's ACCESS website at *http://access.trade.gov.*[5] Further, in accordance with 19 CFR 351.303(f)(l)(i), a copy of each request must be served on the petitioner and each exporter or producer specified in the request.

Commerce will publish in the **Federal Register** a notice of ''Initiation of Administrative Review of Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation'' for requests received by the last day of October 2018. If Commerce does not receive, by the last day of October 2018, a request for review of entries covered by an order, finding, or suspended investigation listed in this notice and for the period identified above, Commerce will instruct CBP to assess antidumping or countervailing duties on those entries at a rate equal to the cash deposit of estimated antidumping or countervailing duties required on those entries at the time of entry, or withdrawal from warehouse, for consumption and to continue to collect the cash deposit previously ordered.

For the first administrative review of any order, there will be no assessment of antidumping or countervailing duties on entries of subject merchandise entered, or withdrawn from warehouse, for consumption during the relevant provisional-measures ''gap'' period of the order, if such a gap period is applicable to the period of review.

This notice is not required by statute but is published as a service to the international trading community.

Dated: October 19, 2018.

James Maeder,

Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations performing the duties of Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2018–23874 Filed 10–31–18; 8:45 am]

BILLING CODE 3510–DS–P

[2] *See also* the Enforcement and Compliance website at *http://trade.gov/enforcement/.*

[3] *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 (November 4, 2013).

[4] In accordance with 19 CFR 351.213(b)(1), parties should specify that they are requesting a review of entries from exporters comprising the entity, and to the extent possible, include the names of such exporters in their request.

[5] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011).

DEPARTMENT OF COMMERCE

International Trade Administration

Meeting of the Renewable Energy and Energy Efficiency Advisory Committee

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of an open meeting.

SUMMARY: The Renewable Energy and Energy Efficiency Advisory Committee (REEEAC) will hold a meeting on Tuesday, November 13, 2018 at the U.S. Department of Commerce Herbert C. Hoover Building (Rm. 1894, Commerce Research Library) in Washington, DC. The meeting is open to the public with registration instructions provided below.

DATES: November 13, 2018, from approximately 9:00 a.m. to 5:00 p.m. Eastern Standard Time (EST). Members of the public wishing to participate must register in advance with Victoria Gunderson at the contact information below by 5:00 p.m. EST on Wednesday, November 7, 2018 in order to pre-register, including any requests to make comments during the meeting or for accommodations or auxiliary aids.

ADDRESSES: To register, please contact Victoria Gunderson, Designated Federal Officer, Office of Energy and Environmental Industries (OEEI), Industry and Analysis, International Trade Administration, U.S. Department of Commerce at (202) 482–7890; email: *Victoria.Gunderson@trade.gov.*

FOR FURTHER INFORMATION CONTACT: Victoria Gunderson, Designated Federal Officer, Office of Energy and Environmental Industries (OEEI), Industry and Analysis International Trade Administration, U.S. Department of Commerce at (202) 482–7890; email: *Victoria.Gunderson@trade.gov.*

SUPPLEMENTARY INFORMATION:

Background: The Secretary of Commerce established the REEEAC pursuant to discretionary authority and in accordance with the Federal Advisory Committee Act, as amended (5 U.S.C. App.), on July 14, 2010. The REEEAC was re-chartered most recently on June 7, 2018. The REEEAC provides

the Secretary of Commerce with consensus advice from the private sector on the development and administration of programs and policies to expand the export competitiveness of U.S. renewable energy and energy efficiency products and services. More information regarding the REEEAC is available online at *http://export.gov/reee/reeeac.*

On November 13, the REEEAC will hold the first in-person meeting of its current charter term. The Committee, with officials from the Department of Commerce and other agencies will discuss major issues affecting the competitiveness of the U.S. renewable energy and energy efficiency industries, determine sub-committee structure, and provide consultation on REEEAC leadership. An agenda will be made available by November 7, 2018 upon request.

The meeting will be open to the public and will be accessible to people with disabilities. All guests are required to register in advance by the deadline identified under the DATE caption. Requests for auxiliary aids must be submitted by the registration deadline. Last minute requests will be accepted but may be impossible to fill.

A limited amount of time before the close of the meeting will be available for oral comments from members of the public attending the meeting. To accommodate as many speakers as possible, the time for public comments will be limited to two to five minutes per person (depending on number of public participants). Individuals wishing to reserve speaking time during the meeting must contact Ms. Gunderson and submit a brief statement of the general nature of the comments, as well as the name and address of the proposed participant by 5:00 p.m. EST on Wednesday, November 7, 2018. If the number of registrants requesting to make statements is greater than can be reasonably accommodated during the meeting, the International Trade Administration may conduct a lottery to determine the speakers. Speakers are requested to submit a copy of their oral comments by email to Ms. Gunderson for distribution to the participants in advance of the meeting.

Any member of the public may submit written comments concerning the REEEAC's affairs at any time before or after the meeting. Comments may be submitted to the Renewable Energy and Energy Efficiency Advisory Committee, c/o: Victoria Gunderson, Designated Federal Officer, Office of Energy and Environmental Industries, U.S. Department of Commerce, 1401 Constitution Avenue NW, Mail Stop: 4053, Washington, DC 20230. To be considered during the meeting, public comments must be transmitted to the REEEAC prior to the meeting. As such, written comments must be received no later than 5:00 p.m. EST on Wednesday, November 7, 2018. Comments received after that date will be distributed to the members but may not be considered at the meeting.

Copies of REEEAC meeting minutes will be available within 30 days following the meeting.

Dated: October 16, 2018.

Man Cho,

Deputy Director, Office of Energy and Environmental Industries.

[FR Doc. 2018–23884 Filed 10–31–18; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

Initiation of Five-Year (Sunset) Reviews

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: In accordance with the Tariff Act of 1930, as amended (the Act), the Department of Commerce (Commerce) is automatically initiating the five-year reviews (Sunset Reviews) of the antidumping and countervailing duty (AD/CVD) order(s) listed below. The International Trade Commission (the Commission) is publishing concurrently with this notice its notice of *Institution of Five-Year Reviews* which covers the same order(s).

DATES: Applicable (November 1, 2018).

FOR FURTHER INFORMATION CONTACT: Commerce official identified in the *Initiation of Review* section below at AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230. For information from the Commission contact Mary Messer, Office of Investigations, U.S. International Trade Commission at (202) 205–3193.

SUPPLEMENTARY INFORMATION:

Background

Commerce's procedures for the conduct of Sunset Reviews are set forth in its *Procedures for Conducting Five-Year (Sunset) Reviews of Antidumping and Countervailing Duty Orders,* 63 FR 13516 (March 20, 1998) and 70 FR 62061 (October 28, 2005). Guidance on methodological or analytical issues relevant to Commerce's conduct of Sunset Reviews is set forth in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Duty Proceedings; Final Modification,* 77 FR 8101 (February 14, 2012).

Initiation of Review

In accordance with section 751(c) of the Act and 19 CFR 351.218(c), we are initiating the Sunset Reviews of the following antidumping and countervailing duty order(s):

DOC case No.	ITC case No.	Country	Product	Commerce contact
A–570–910	731–TA–1116	China	Circular Welded Carbon, Quality Steel Pipe, (2nd Review).	Matthew Renkey, (202) 482–2312.
C–570–911	701–TA–447	China	Circular Welded Carbon, Quality Steel Pipe, (2nd Review).	Joshua Poole, (202) 482–1293.
A–427–818	731–TA–909	France	Low Enriched Uranium, (3rd Review).	Jacqueline Arrowsmith, (202) 482–5255.

Filing Information

As a courtesy, we are making information related to sunset proceedings, including copies of the pertinent statute and Commerces's regulations, Commerce's schedule for Sunset Reviews, a listing of past revocations and continuations, and current service lists, available to the public on Commerce's website at the following address: *http://enforcement.trade.gov/sunset/.* All submissions in these Sunset Reviews must be filed in accordance with Commerce's regulations regarding format, translation, and service of documents. These rules, including electronic filing requirements via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System

(ACCESS), can be found at 19 CFR 351.303.[1]

Any party submitting factual information in an AD/CVD proceeding must certify to the accuracy and completeness of that information.[2] Parties must use the certification formats provided in 19 CFR 351.303(g).[3] Commerce intends to reject factual submissions if the submitting party does not comply with applicable revised certification requirements.

On April 10, 2013, Commerce modified two regulations related to AD/CVD proceedings: The definition of factual information (19 CFR 351.102(b)(21)), and the time limits for the submission of factual information (19 CFR 351.301).[4] Parties are advised to review the final rule, available at *http://enforcement.trade.gov/frn/2013/1304frn/2013-08227.txt,* prior to submitting factual information in these segments. To the extent that other regulations govern the submission of factual information in a segment (such as 19 CFR 351.218), these time limits will continue to be applied. Parties are also advised to review the final rule concerning the extension of time limits for submissions in AD/CVD proceedings, available at *http://enforcement.trade.gov/frn/2013/1309frn/2013-22853.txt,* prior to submitting factual information in these segments.[5]

Letters of Appearance and Administrative Protective Orders

Pursuant to 19 CFR 351.103(d), Commerce will maintain and make available a public service list for these proceedings. Parties wishing to participate in any of these five-year reviews must file letters of appearance as discussed at 19 CFR 351.103(d)). To facilitate the timely preparation of the public service list, it is requested that those seeking recognition as interested parties to a proceeding submit an entry of appearance within 10 days of the publication of the Notice of Initiation. Because deadlines in Sunset Reviews can be very short, we urge interested parties who want access to proprietary information under administrative protective order (APO) to file an APO application immediately following publication in the **Federal Register** of this notice of initiation. Commerce's regulations on submission of proprietary information and eligibility to receive access to business proprietary information under APO can be found at 19 CFR 351.304–306.

Information Required From Interested Parties

Domestic interested parties, as defined in section 771(9)(C), (D), (E), (F), and (G) of the Act and 19 CFR 351.102(b), wishing to participate in a Sunset Review must respond not later than 15 days after the date of publication in the **Federal Register** of this notice of initiation by filing a notice of intent to participate. The required contents of the notice of intent to participate are set forth at 19 CFR 351.218(d)(1)(ii). In accordance with Commerce's regulations, if we do not receive a notice of intent to participate from at least one domestic interested party by the 15-day deadline, Commerce will automatically revoke the order without further review.[6]

If we receive an order-specific notice of intent to participate from a domestic interested party, Commerce's regulations provide that *all parties* wishing to participate in a Sunset Review must file complete substantive responses not later than 30 days after the date of publication in the **Federal Register** of this notice of initiation. The required contents of a substantive response, on an order-specific basis, are set forth at 19 CFR 351.218(d)(3). Note that certain information requirements differ for respondent and domestic parties. Also, note that Commerce's information requirements are distinct from the Commission's information requirements. Consult Commerce's regulations for information regarding Commerce's conduct of Sunset Reviews. Consult Commerce's regulations at 19 CFR part 351 for definitions of terms and for other general information concerning antidumping and countervailing duty proceedings at Commerce.

This notice of initiation is being published in accordance with section 751(c) of the Act and 19 CFR 351.218(c).

Dated: October 19, 2018.

James Maeder,

Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations performing the duties of Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2018–23875 Filed 10–31–18; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See also Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011).

[2] *See* section 782(b) of the Act.

[3] *See also Certification of Factual Information to Import Administration During Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) (*Final Rule*). Answers to frequently asked questions regarding the *Final Rule* are available at *http://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.*

[4] *See Definition of Factual Information and Time Limits for Submission of Factual Information: Final Rule,* 78 FR 21246 (April 10, 2013).

[5] *See Extension of Time Limits,* 78 FR 57790 (September 20, 2013).

[6] *See* 19 CFR 351.218(d)(1)(iii).

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Reporting Requirements for Commercial Fisheries Authorization Under Section 118 of the Marine Mammal Protection Act

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before December 31, 2018.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW, Washington, DC 20230 (or via the internet at *pracomments@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Jaclyn Taylor, (301) 427–8402 or *Jaclyn.Taylor@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for an extension of a currently approved information collection.

Reporting injury to and/or mortalities of marine mammals is mandated under Section 118 of the Marine Mammal Protection Act. This information is required to determine the impacts of commercial fishing on marine mammal populations. This information is also used to categorize commercial fisheries into Categories I, II, or III. Participants in the first two categories must be

authorized to take marine mammals, while those in Category III are exempt from that requirement. All three categories must report injuries or mortalities on a National Marine Fisheries Service form.

II. Method of Collection

Respondents have a choice of either electronic or paper forms. Methods of submittal include online forms, email of electronic or scanned forms, mail and facsimile transmission of paper forms.

III. Data

OMB Control Number: 0648–0292.

Form Number(s): None.

Type of Review: Regular submission (extension of currently approved collection).

Affected Public: Business or other for-profit organizations; Individuals or households; State, local, or tribal government.

Estimated Number of Respondents: 200.

Estimated Time per Response: 15 minutes.

Estimated Total Annual Burden Hours: 50.

Estimated Total Annual Cost to Public: $0 in recordkeeping/reporting costs.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: October 29, 2018.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2018–23864 Filed 10–31–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG514

Atlantic Highly Migratory Species; Atlantic Shark Management Measures; 2019 Research Fishery

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

ACTION: Notice of intent; request for applications.

SUMMARY: NMFS announces its request for applications for the 2019 shark research fishery from commercial shark fishermen with directed or incidental shark limited access permits. The shark research fishery allows for the collection of fishery-dependent and biological data for future stock assessments and to meet the research objectives of the Agency. The only commercial vessels authorized to land sandbar sharks are those participating in the shark research fishery. Shark research fishery permittees may also land other large coastal sharks (LCS), small coastal sharks (SCS), smoothhound, and pelagic sharks. Commercial shark fishermen who are interested in participating in the shark research fishery need to submit a completed Shark Research Fishery Permit Application in order to be considered.

DATES: Shark Research Fishery Applications must be received no later than December 1, 2018.

ADDRESSES: Please submit completed applications to the HMS Management Division at:

- *Mail:* Attn: Lauren Latchford, HMS Management Division (F/SF1), NMFS, 1315 East-West Highway, Silver Spring, MD 20910.
- *Email: NMFS.Research.Fishery@noaa.gov.*

For copies of the Shark Research Fishery Permit Application, please write to the HMS Management Division at the address listed above, call (301) 427–8503 (phone), or email a request to *NMFS.Research.Fishery@noaa.gov.* Copies of the Shark Research Fishery Application are also available at the HMS website at *https://www.fisheries.noaa.gov/atlantic-highly-migratory-species/atlantic-highly-migratory-species-permits-and-reporting-forms.* Additionally, please be advised that your application may be released under the Freedom of Information Act.

FOR FURTHER INFORMATION CONTACT: Karyl Brewster-Geisz, Guý DuBeck, or Lauren Latchford at (301) 427–8503 (phone) or email *NMFS.research.fishery@noaa.gov.*

SUPPLEMENTARY INFORMATION: The Atlantic shark fisheries are managed under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). The 2006 Consolidated HMS Fishery Management Plan (FMP), as amended, is implemented by regulations at 50 CFR part 635.

The shark research fishery was established, in part, to maintain time series data for stock assessments and to meet NMFS' research objectives. Since the shark research fishery was established in 2008, the research fishery has allowed for: The collection of fishery-dependent data for current and future stock assessments; the operation of cooperative research to meet NMFS' ongoing research objectives; the collection of updated life-history information used in the sandbar shark (and other species) stock assessment; the collection of data on habitat preferences that might help reduce fishery interactions through bycatch mitigation; evaluation of the utility of the mid-Atlantic closed area on the recovery of dusky sharks and collection of hook-timer and pop-up satellite archival tag (PSAT) information to determine at-vessel and post-release mortality of dusky sharks; and collection of sharks to determine the weight conversion factor from dressed weight to whole weight.

The shark research fishery allows selected commercial fishermen the opportunity to earn revenue from selling additional sharks, including sandbar sharks. Only the commercial shark fishermen selected to participate in the shark research fishery are authorized to land sandbar sharks subject to the sandbar quota available each year. The base quota is 90.7 metric tons (mt) dressed weight (dw) per year, although this number may be reduced in the event of overharvests, if any. The selected shark research fishery permittees will also be allowed to land other LCS, SCS, smoothhound, and pelagic sharks consistent with any restrictions established on their shark research fishery permit. Generally, the shark research fishery permits are valid only for the calendar year for which they are issued.

The specific 2019 trip limits and number of trips per month will depend on the availability of funding, number of selected vessels, the availability of observers, the available quota, and the objectives of the research fishery, and will be included in the permit terms at

time of issuance. The number of participants in the research fishery changes each year. In 2018, six fishermen were chosen to participate. From 2008 through 2018, there has been an average of seven participants each year with the range from five to eleven. The number of trips allowed per month can change, but in the last few years this number has remained constant with participating vessels on average been able to take one trip per month. However, the number of trips taken per month are limited by the scientific and research needs of the Agency and the number of NMFS-approved observers available. Participants may also be limited on the amount of gear they can deploy on a given set (*e.g.,* number of hooks and sets, soak times, length of longline). In recent years, participants have been limited to one feeler set with a maximum of 150 hooks and one main set with a maximum of 300 hooks. These hook limits may change both between years and during the year depending on research goals and bycatch limits.

In the 2018 fishing season, NMFS split 90 percent of the sandbar and LCS research fishery quotas equally among selected participants, with each vessel allocated 13.6 mt dw (29,994 lb dw) of sandbar shark research fishery quota and 7.5 mt dw (16,535 lb dw) of other LCS research fishery quota. The remaining quota was held in reserve to ensure the overall sandbar and LCS research fishery quotas were not exceeded. NMFS also established a regional dusky bycatch limit, which was implemented in 2013, specific to this small research fishery, where once three or more dusky sharks were brought to the vessel dead in any of four regions across the Gulf of Mexico and Atlantic through the entire year, any shark research fishery permit holder in that region was not able to soak their gear for longer than 3 hours. If, after the change in soak time, there were two additional dusky shark interactions (alive or dead) observed, shark research fishery permit holders were not able to make a trip in that region for the remainder of the year, unless otherwise permitted by NMFS. There were slightly different measures established for shark research fishery participants in the mid-Atlantic shark closed area in order to allow NMFS observers to place satellite archival tags on dusky sharks and collect other scientific information on dusky sharks while also minimizing any dusky shark mortality.

Participants were also required to land any dead sharks, unless they were a prohibited species, in which case they were required to discard them. All prohibited species must be released, unless the observer requests that the shark be retained for research purposes. If the regional non-blacknose SCS, blacknose, and/or pelagic shark commercial management group quotas were closed, then any shark research fishery permit holder fishing in the region was required to discard all of the species from the closed management groups regardless of condition. Any sharks, except prohibited species or species from closed commercial management groups, caught and brought to the vessel alive could be released alive or landed. In addition, as established in the shark research fishery permits, participants were restricted by the number of longline sets as well as the number of hooks they could deploy and have on board the vessel. The vessels participating in the shark research fishery took on average 12 trips in 2017, but the timing, and number of the trips varied based on seasonal availability of certain species and individual allocated quotas.

In order to participate in the shark research fishery, commercial shark fishermen need to submit a completed Shark Research Fishery Application by the deadline noted above (see **DATES**) showing that the vessel and owner(s) meet the specific criteria outlined below.

Research Objectives

Each year, the research objectives are developed by a shark board, which is comprised of representatives within NMFS, including representatives from the Southeast Fisheries Science Center (SEFSC) Panama City Laboratory, Northeast Fisheries Science Center Narragansett Laboratory, the Southeast Regional Office Protected Resources Division, and the HMS Management Division. The research objectives for 2019 are based on various documents, including the 2012 Biological Opinion for the Continued Authorization of the Atlantic Shark Fisheries and the Federal Authorization of a Smoothhound Fishery, as well as recent stock assessments for the U.S. South Atlantic blacknose, U.S. Gulf of Mexico blacknose, U.S. Gulf of Mexico blacktip, sandbar, and dusky sharks (all these stock assessments can be found at *http://sedarweb.org/*). The 2019 research objectives are:

- Collect reproductive, length, sex, and age data from sandbar and other sharks throughout the calendar year for species-specific stock assessments;
- Monitor the size distribution of sandbar sharks and other species captured in the fishery;
- Continue on-going tagging shark programs for identification of migration corridors and stock structure using dart and/or spaghetti tags;
- Maintain time-series of abundance from previously derived indices for the shark bottom longline observer program;
- Sample fin sets (*e.g.,* dorsal, pectoral) from prioritized species to further develop fin identification guides;
- Acquire fin-clip samples of all shark and other species for genetic analysis;
- Attach satellite archival tags to endangered smalltooth sawfish to provide information on critical habitat and preferred depth, consistent with the requirements listed in the take permit issued under section 10 of the Endangered Species Act to the SEFSC observer program;
- Attach satellite archival tags to prohibited dusky and other sharks, as needed, to provide information on daily and seasonal movement patterns, and preferred depth;
- Evaluate hooking mortality and post-release survivorship of dusky, hammerhead, blacktip, and other sharks using hook-timers and temperature-depth recorders;
- Evaluate the effects of controlled gear experiments in order to determine the effects of potential hook changes to prohibited species interactions and fishery yields;
- Examine the size distribution of sandbar and other sharks captured throughout the fishery including in the Mid-Atlantic shark time/area closure off the coast of North Carolina from January 1 through July 31;
- Develop allometric and weight relationships of selected species of sharks (*e.g.,* hammerhead, sandbar, blacktip shark); and
- Collect samples such as liver and muscle plugs for stable isotope analysis as a part of a trophic level-based ecosystem study.

Selection Criteria

Shark Research Fishery Permit Applications will only be accepted from commercial shark fishermen who hold a current directed or incidental shark limited access permit. While incidental permit holders are welcome to submit an application, to ensure that an appropriate number of sharks are landed to meet the research objectives for this year, NMFS will give priority to directed permit holders as recommended by the shark board. As such, qualified incidental permit holders will be selected only if there are not enough qualified directed permit holders to meet research objectives.

The Shark Research Fishery Permit Application includes, but is not limited to, a request for the following information: Type of commercial shark permit possessed; past participation and availability in the commercial shark fishery (not including sharks caught for display); past involvement and compliance with HMS observer programs per 50 CFR 635.7; past compliance with HMS regulations at 50 CFR part 635; past and present availability to participate in the shark research fishery year-round; ability to fish in the regions and season requested; ability to attend necessary meetings regarding the objectives and research protocols of the shark research fishery; and ability to carry out the research objectives of the Agency. Preference will be given to those applicants who are willing and available to fish year-round and who affirmatively state that they intend to do so, in order to ensure the timely and accurate data collection NMFS needs to meet this year's research objectives. An applicant who has been charged criminally or civilly (*e.g.,* issued a Notice of Violation and Assessment (NOVA) or Notice of Permit Sanction) for any HMS-related violation will not be considered for participation in the shark research fishery. In addition, applicants who were selected to carry an observer in the previous two years for any HMS fishery, but failed to contact NMFS to arrange the placement of an observer as required per 50 CFR 635.7, will not be considered for participation in the 2019 shark research fishery. Applicants who were selected to carry an observer in the previous two years for any HMS fishery and failed to comply with all the observer regulations per 50 CFR 635.7 will also not be considered. Exceptions will be made for vessels that were selected for HMS observer coverage but did not fish in the quarter when selected and thus did not require an observer. Applicants who do not possess a valid USCG safety inspection decal when the application is submitted will not be considered. Applicants who have been non-compliant with any of the HMS observer program regulations in the previous two years, as described above, may be eligible for future participation in shark research fishery activities by demonstrating two subsequent years of compliance with observer regulations at 50 CFR 635.7.

Selection Process

The HMS Management Division will review all submitted applications and develop a list of qualified applicants from those applications that are deemed complete. A qualified applicant is an applicant that has submitted a complete application by the deadline (see **DATES**) and has met the selection criteria listed above. Qualified applicants are eligible to be selected to participate in the shark research fishery for 2019. The HMS Management Division will provide the list of qualified applicants without identifying information to the SEFSC. The SEFSC will then evaluate the list of qualified applicants and, based on the temporal and spatial needs of the research objectives, the availability of observers, the availability of qualified applicants, and the available quota for a given year, will randomly select qualified applicants to conduct the prescribed research. Where there are multiple qualified applicants that meet the criteria, permittees will be randomly selected through a lottery system. If a public meeting is deemed necessary, NMFS will announce details of a public selection meeting in a subsequent **Federal Register** notice.

Once the selection process is complete, NMFS will notify the selected applicants and issue the shark research fishery permits. The shark research fishery permits will be valid through December 31, 2019, unless otherwise specified. If needed, NMFS will communicate with the shark research fishery permit holders to arrange a captain's meeting to discuss the research objectives and protocols. NMFS usually holds mandatory captain's meetings before observers are placed on vessels and may hold one for the 2019 shark research fishery in late 2018 or early 2019. Once the fishery starts, the shark research fishery permit holders must contact the NMFS observer coordinator to arrange the placement of a NMFS-approved observer for each shark research trip. Additionally, selected applicants are expected to allow observers the opportunity to perform their duties as required and assist observers as necessary.

A shark research fishery permit will only be valid for the vessel and owner(s) and terms and conditions listed on the permit, and, thus, cannot be transferred to another vessel or owner(s). Shark research fishery permit holders must carry a NMFS-approved observer in order to land sandbar sharks. Issuance of a shark research permit does not guarantee that the permit holder will be assigned a NMFS-approved observer on any particular trip. Rather, issuance indicates that a vessel may be issued a NMFS-approved observer for a particular trip, and on such trips, may be allowed to harvest Atlantic sharks, including sandbar sharks, in excess of the retention limits described in 50 CFR 635.24(a). These retention limits will be based on available quota, number of vessels participating in the 2019 shark research fishery, the research objectives set forth by the shark board, the extent of other restrictions placed on the vessel, and may vary by vessel and/or location. When not operating under the auspices of the shark research fishery, the vessel would still be able to land LCS, SCS, and pelagic sharks subject to existing retention limits on trips without a NMFS-approved observer.

NMFS annually invites commercial shark permit holders (directed and incidental) to submit an application to participate in the shark research fishery. Permit applications can be found on the HMS Management Division's website at *https://www.fisheries.noaa.gov/atlantic-highly-migratory-species/atlantic-highly-migratory-species-permits-and-reporting-forms* or by calling (301) 427–8503. Final decisions on the issuance of a shark research fishery permit will depend on the submission of all required information by the deadline (see **DATES**), and NMFS' review of applicant information as outlined above. The 2019 shark research fishery will start after the opening of the shark fishery and under available quotas as published in a separate **Federal Register** final rule.

Dated: October 29, 2018.

Karen H. Abrams,

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

[FR Doc. 2018–23901 Filed 10–31–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

New York and New Jersey Harbor Anchorages General Reevaluation Study NEPA Scoping Meeting and Public Comment Period

AGENCY: Department of the Army, U.S. Army Corps of Engineers, DoD.

ACTION: Notice of Intent/NEPA Scoping meeting and public comment period.

SUMMARY: In accordance with all applicable laws and regulations, the U.S. Army Corps of Engineers (USACE) plans to prepare a General Reevaluation Study (GRR) with an integrated Environmental Impact Statement (EIS) to evaluate environmental impacts from reasonable project alternatives and to determine the potential for significant impacts related to the improvement of the anchorages included in the Federal navigation project to take into account

changed conditions and/or assumptions since the original feasibility study was completed in 2000. The GRR will address the need for anchorage areas capable of safely accommodating the vessels navigating the anchorages at present and reasonably projected to be navigating them in the future; or find that no plan is currently justified.

DATES: Scoping comments may be submitted until December 10, 2018.

ADDRESSES: The public is invited to submit NEPA scoping comments at the meeting and/or submit comments to Mr. David Schulte, Department of the Army, U.S. Army Corps of Engineers, Norfolk District, Fort Norfolk, 803 Front St., Norfolk, VA 23510 or via email: *David.M.Schulte@usace.army.mil.* The project title and the commenter's contact information should be included with submitted comments.

FOR FURTHER INFORMATION CONTACT: David Schulte, (757) 201–7007.

SUPPLEMENTARY INFORMATION: Applicable laws and regulations are section 102(2)(C) of the National Environmental Policy Act (NEPA) of 1969, as amended, 42 U.S.C. 4321–4370, as implemented by the Council on Environmental Quality Regulations (40 CFR parts 1500–1508). The primary problem is that existing Federal anchorages in the harbor are insufficient in meeting the variety of functions (ex. security and U.S. Coast Guard inspections, lightering, bunkering/refueling, waiting areas, and emergency ''bailout'' areas) they are used for as part of normal harbor operations, which reduces vessel safety and cargo transportation efficiency. Multiple issues have been identified by key harbor users and stakeholders. There is not enough anchorage area to accommodate all of the vessels that need to anchor for various reasons. The dimensions of existing anchorages cannot accommodate vessels larger than 1100 foot LOA (length overall) which is a significant portion of the vessels that regularly call on the harbor and anchored vessels regularly swing out into the navigation channel. Vessels are currently forced to wait outside the harbor in the ocean due to a lack of anchorage availability and/or anchorage areas designed for larger vessels.

USACE is the lead federal agency and the Port Authority of New York and New Jersey will be the non-federal sponsor for the study. The GRR will address the primary problem of the New York and New Jersey Harbor Anchorages by studying all reasonable alternatives and determine the Federal interest in cost-sharing for those alternatives.

As required by Council on Environmental Quality's Principles, Requirements and Guidelines for Water and Land Related Resources Implementation Studies all reasonable alternatives to the proposed Federal action that meet the purpose and need will be considered in the EIS. These alternatives will include no action and a range of reasonable alternatives for improving navigation in the New York & New Jersey Harbor Anchorages.

Scoping/Public Involvement. The public NEPA scoping meeting will be held on November 8, 2018, from 5 p.m.-8 p.m. It will be held at the GSA Building, conference rooms 1–3 on the 30th floor, at 290 Broadway, New York, NY 10007. Federal, state, and local agencies, Indian tribes, and the public are invited to provide scoping comments to identify issues and potentially significant effects to be considered in the analysis.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 2018–23879 Filed 10–31–18; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

Notice of Availability of the Draft Integrated Feasibility Report Draft Environmental Impact Statement/Draft Environmental Impact Report (DEIS/DEIR) for Westminster, East Garden Grove, California Flood Risk Management Study

AGENCY: Department of the Army, U.S. Army Corps of Engineers, DOD.

ACTION: Notice of availability.

SUMMARY: The U.S. Army Corps of Engineers (USACE), in cooperation with Orange County Public Works, Orange County, CA announces the availability of a Draft Integrated Feasibility Report (Draft IFR) including Feasibility Report and Environmental Impact Statement (EIS) for the Westminster, East Garden Grove, California Flood Risk Management Study for review and comment. The Draft IFR presents alternatives to address flood risk to the residents of the communities in the Westminster watershed. The purpose of this study is to evaluate the flood risk within the Westminster watershed that is primarily attributable to drainage channels overwhelmed with having to collect and convey more surface runoff downstream towards eventual discharge into the Pacific Ocean than what they were designed for. USACE evaluated and analyzed various flood control measures and formulated alternatives specifically for the Westminster watershed. USACE also evaluated the potential impacts of the alternatives and ways to minimize such impacts. A Notice of Intent to prepare the Draft EIS was published on January 13, 2006. A public scoping meeting was conducted on January 25, 2006 in the City of Garden Grove, CA.

DATES: The Draft IFR is available for a 45-day public review period, pursuant to the National Environmental Policy Act (NEPA), from Friday, October 19, 2018, through Monday, December 3, 2018.

ADDRESSES: Comments will be accepted through the project email address at *westminster_comments@usace.army.mil,* by letter and at public meetings. See **SUPPLEMENTARY INFORMATION** section for instructions on how to submit public comments, public meeting dates, and public meeting locations.

FOR FURTHER INFORMATION CONTACT: For further information and/or questions about Westminster, East Garden Grove, please contact Michael Padilla, Program Manager, by mail: U.S. Army Corps of Engineers, Chicago District, 231 South LaSalle Street, Suite 1500, Chicago, IL 60604, by phone: 312–846–5427; or by email: *Michael.C.Padilla@usace.army.mil.*

SUPPLEMENTARY INFORMATION:

1. Background. The study is being conducted in accordance with the study resolution adopted by the Committee on Public Works, House of Representatives Committee on Public Works on May 8, 1964 (Flood Control Act of 1938). The goal of the Westminster, East Garden Grove Study is to identify sustainable flood risk management solutions within the Westminster watershed to reduce flooding caused by overtopping of the C05/C06 and C02/C04 channel systems. USACE conducted the Westminster Study in consultation with other Federal agencies, Native American tribes, state agencies, local governments, and non-governmental organizations.

2. The Draft IFR. The Draft IFR includes an analysis of four alternatives, including the No Action Alternative, to determine which plan or plans would merit further consideration for federal participation. The documentation also includes an analysis of the impacts of each alternative on existing resources within the Westminster watershed. The alternatives were developed to a level of detail sufficient to identify a Tentatively Selected Plan (TSP), as well as a Locally Preferred Plan (LPP). The TSP is the

Minimum Channel Modifications Alternative, which reduces flood risk by lining the existing drainage channels with concrete, thus increasing conveyance efficiency. The LPP is the Maximum Channel Modifications Alternative, which reduces flood risk by altering the geometry of existing drainage channels to increase conveyance efficiency and storage capacity. Both of these plans include additional downstream measures to address the impacts of increased flood flow conveyance resulting from the channel modifications. The downstream measures include increasing the span of Warner Avenue Bridge, replacing the tide gates on C05, and constructing a floodwall along the Pacific Coast Highway at Outer Bolsa Bay. Compatible nonstructural measures were also included in the TSP and LPP to lessen the life safety risk associated with flooding in the project area. Each plan will require mitigation to address the loss of habitat.

3. Public Participation. USACE will accept comments related to the Draft IFR until December 3, 2018. Comments may be submitted in the following ways:

- *Project Email Address:* Send comment and any attachments to *westminster_comments@usace.army.mil.*
- *Mail:* Send comments to Orange County Public Works, ATTN: Justin Golliher, 300 North Flower Street, Santa Ana, CA 92703. Comments must be postmarked by December 3, 2018.
- *Public Meetings:* Public meetings are scheduled for November 7 and November 8, 2018. The public review meeting on November 7, 2018, is from 6:30 p.m. to 9:00 p.m. at the City of Westminster City Hall. The address is 8200 Westminster Boulevard, Westminster, CA 92683. The public review meeting on November 8, 2018, is from 6:30 p.m. to 9:00 p.m. at the Meadowlark Golf Course. The address is 16782 Graham Street, Huntington Beach, CA 92649. The public meetings will allow participants the opportunity to comment on the Draft IFR. A stenographer will document oral comments at the public meetings.

Public meetings will begin with a brief presentation regarding the study and the formulated alternatives followed by an oral comment period. During each meeting, USACE personnel will also collect written comments on comment cards. Additional information about public meetings including dates, times and locations will be posted on the Westminster project website at *https://www.lrc.usace.army.mil/Missions/Civil-Works-Projects/Westminster-East-Garden-Grove/.*

4. Authority. This action is being conducted in accordance with the study resolution adopted by the Committee on Public Works, House of Representatives Committee on Public Works on May 8, 1964 (Flood Control Act of 1938), and the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4321, *et seq.,* as amended.

Dated: 25 October 2018.

Susanne J. Davis,

Chief, Planning Branch, CELRC–PMD–PB.

[FR Doc. 2018–23880 Filed 10–31–18; 8:45 am]

BILLING CODE 3720–59–P

DEFENSE NUCLEAR FACILITIES SAFETY BOARD

Sunshine Act Meetings

TIME AND DATE: 2:00 p.m., November 5, 2018.

PLACE: Defense Nuclear Facilities Safety Board, 625 Indiana Avenue NW, Suite 700, Washington, DC 20004.

STATUS: Closed. During the closed meeting, the Board Members will discuss issues dealing with potential Recommendations to the Secretary of Energy. The Board is invoking the exemptions to close a meeting described in 5 U.S.C. 552b(c)(3) and (9)(B) and 10 CFR 1704.4(c) and (h). The Board has determined that it is necessary to close the meeting since conducting an open meeting is likely to disclose matters that are specifically exempted from disclosure by statute, and/or be likely to significantly frustrate implementation of a proposed agency action. In this case, the deliberations will pertain to potential Board Recommendations which, under 42 U.S.C. 2286d(b) and (h)(3), may not be made publicly available until after they have been received by the Secretary of Energy or the President, respectively.

MATTERS TO BE CONSIDERED: The meeting will proceed in accordance with the closed meeting agenda which is posted on the Board's public website at *www.dnfsb.gov.* Technical staff may present information to the Board. The Board Members are expected to conduct deliberations regarding potential Recommendations to the Secretary of Energy.

CONTACT PERSON FOR MORE INFORMATION: Glenn Sklar, General Manager, Defense Nuclear Facilities Safety Board, 625 Indiana Avenue NW, Suite 700, Washington, DC 20004–2901, (800) 788–4016. This is a toll-free number.

Dated: October 30, 2018.

Bruce Hamilton,

Chairman.

[FR Doc. 2018–23977 Filed 10–30–18; 11:15 am]

BILLING CODE 3670–01–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2018–ICCD–0115]

Agency Information Collection Activities; Comment Request; Student Assistance General Provisions—Readmission for Servicemembers

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before December 31, 2018.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2018–ICCD–0115. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 550 12th Street SW, PCP, Room 9086, Washington, DC 20202–0023.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202–377–4018.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection

requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Student Assistance General Provisions—Readmission for Servicemembers.

OMB Control Number: 1845–0095.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: Individuals or Households; Private Sector; State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 4,570.

Total Estimated Number of Annual Burden Hours: 1,531.

Abstract: The Department of Education is requesting an extension of the current information collection. These regulations identify the requirements under which an institutions must readmit servicemembers with the same academic status they held at the institutions when they last attended or were accepted for attendance. The regulations require institutions to charge readmitted servicemembers, for the first academic year of their return, the same institutions charges they were charged for the academic year during which they left the institution to fulfill a service requirement in the uniformed services.

Dated: October 29, 2018.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2018–23913 Filed 10–31–18; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

[FE Docket No. 16–144–LNG]

Driftwood LNG LLC: Supplement to Application for Long-Term, Multi-Contract Authorization To Export Liquefied Natural Gas to Non-Free Trade Agreement Nations for a 20-Year Period

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of Supplement.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy (DOE) gives notice of receipt of a March 5, 2018 filing by Driftwood LNG LLC (Driftwood LNG), entitled ''Supplement to Long-Term Authorization and Application for Long-Term Authorization'' (Supplement). Previously, on September 28, 2016, Driftwood LNG filed an application (Application) in this proceeding requesting authorization to export domestically produced liquefied natural gas (LNG) from its proposed Facility in Calcasieu Parish, Louisiana, to any country with which the United States does not have a free trade agreement (FTA) requiring national treatment for trade in natural gas, and with which trade is not prohibited by U.S. law or policy (non-FTA countries). In relevant part, the Supplement seeks to amend the non-FTA export volume originally requested in the Application. Specifically, Driftwood LNG seeks to decrease its requested export volume to the equivalent of 1,415.3 billion cubic feet per year (Bcf/yr) of natural gas (3.88 Bcf/day)—which Driftwood LNG states is equivalent to 27.6 million metric tons per annum (mtpa) of LNG based on its conversion factor.

DATES: Protests, motions to intervene or notices of intervention, as applicable, requests for additional procedures, and written comments are to be filed using procedures detailed in the *Public Comment Procedures* section no later than 4:30 p.m., Eastern time, November 21, 2018.

ADDRESSES:

Electronic Filing by email: fergas@hq.doe.gov.

Regular Mail, U.S. Department of Energy (FE–34), Office of Regulation, Analysis, and Engagement, Office of Fossil Energy, P.O. Box 44375, Washington, DC 20026–4375.

Hand Delivery or Private Delivery Services (*e.g.,* FedEx, UPS, etc.), U.S. Department of Energy (FE–34), Office of Regulation, Analysis, and Engagement, Office of Fossil Energy, Forrestal Building, Room 3E–042, 1000 Independence Avenue SW, Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT: Larine Moore or Benjamin Nussdorf, U.S. Department of Energy (FE–34), Office of Regulation, Analysis, and Engagement, Office of Fossil Energy, Forrestal Building, Room 3E–042, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–9478; (202) 586–7893. Cassandra Bernstein, U.S. Department of Energy (GC–76), Office of the Assistant General Counsel for Electricity and Fossil Energy, Forrestal Building, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–9793.

SUPPLEMENTARY INFORMATION: In its pending Application filed on September 28, 2016, Driftwood LNG sought authorization to export LNG in a volume of 26 mtpa, equivalent to 1,496.5 Bcf/yr of natural gas (4.1 Bcf/day). In this Supplement, Driftwood LNG seeks to decrease its requested export volume to the equivalent of 1,415.3 Bcf/yr of natural gas (3.88 Bcf/day). Driftwood LNG states that the grant of this Supplement will align its requested non-FTA export volume with the optimized estimated LNG production capacity of the Facility. Driftwood LNG states that, on February 15, 2018, it submitted a similar filing to the Federal Energy Regulatory Commission (Docket No. CP17–117–000) to clarify the LNG production capacity of the Facility. Driftwood LNG further asserts that no changes to the design of the Facility are required or proposed to achieve the amended production capacity.

Additional details can be found in Driftwood LNG's filing, posted on the DOE/FE website at: *https://www.energy.gov/sites/prod/files/2018/04/f50/DWLNG16-144sup.pdf.*

Protests, motions to intervene, notices of intervention, and written comments addressing the Supplement are invited.

DOE/FE Evaluation

The Supplement will be reviewed in conjunction with DOE/FE's review of Driftwood LNG's pending Application pursuant to section 3(a) of the NGA, 15 U.S.C. 717b(a).[1] DOE will consider any issues required by law or policy. DOE will consider domestic need for the natural gas, as well as any other issues determined to be appropriate, including

[1] In the Supplement, Driftwood LNG also asks DOE/FE to amend its existing LNG export authorization to FTA countries. *See Driftwood LNG LLC,* DOE/FE Order No. 3968, FE Docket No. 16–144–LNG, Order Granting Long-Term, Multi-Contract Authorization to Export Liquefied Natural Gas by Vessel from the Proposed Driftwood LNG Facility in Calcasieu Parish, Louisiana, to Free Trade Agreement Nations (Feb. 28, 2017). That action is not subject to this Notice, and DOE/FE will address it separately pursuant to section 3(c) of the NGA, 15 U.S.C. 717b(c).

whether the arrangement is consistent with DOE's policy of promoting competition in the marketplace by allowing commercial parties to freely negotiate their own trade arrangements. As part of this analysis, DOE will consider one or more of the following studies examining the cumulative impacts of exporting domestically produced LNG:

- *Effect of Increased Levels of Liquefied Natural Gas on U.S. Energy Markets,* conducted by the U.S. Energy Information Administration upon DOE's request (2014 EIA LNG Export Study); [2]
- *The Macroeconomic Impact of Increasing U.S. LNG Exports,* conducted jointly by the Center for Energy Studies at Rice University's Baker Institute for Public Policy and Oxford Economics, on behalf of DOE (2015 LNG Export Study); [3] and
- *Macroeconomic Outcomes of Market Determined Levels of U.S. LNG Exports,* conducted by NERA Economic Consulting on behalf of DOE (2018 LNG Export Study).[4]

Additionally, DOE will consider the following environmental documents:

- *Addendum to Environmental Review Documents Concerning Exports of Natural Gas From the United States,* 79 FR 48132 (Aug. 15, 2014); [5] and
- *Life Cycle Greenhouse Gas Perspective on Exporting Liquefied Natural Gas from the United States,* 79 FR 32260 (June 4, 2014).[6]

Parties that may oppose this Supplement should address these issues and documents in their comments and/or protests, as well as other issues deemed relevant to the Supplement.

The National Environmental Policy Act (NEPA), 42 U.S.C. 4321 *et seq.,* requires DOE to give appropriate consideration to the environmental effects of its proposed decisions. No final decision will be issued in this proceeding until DOE has met its environmental responsibilities.

[2] The 2014 EIA LNG Export Study, published on Oct. 29, 2014, is available at: *https://www.eia.gov/analysis/requests/fe/.*

[3] The 2015 LNG Export Study, dated Oct. 29, 2015, is available at: *http://energy.gov/sites/prod/files/2015/12/f27/20151113_macro_impact_of_lng_exports_0.pdf.*

[4] The 2018 LNG Export Study, dated June 7, 2018, is available at: *https://www.energy.gov/sites/prod/files/2018/06/f52/Macroeconomic%20LNG%20Export%20Study%202018.pdf.* DOE is currently evaluating public comments received on this Study (83 FR 27314).

[5] The Addendum and related documents are available at: *https://www.energy.gov/sites/prod/files/2014/08/f18/Addendum.pdf.*

[6] The Life Cycle Greenhouse Gas Report is available at: *http://energy.gov/fe/life-cycle-greenhouse-gas-perspective-exporting-liquefied-natural-gas-united-states.*

Public Comment Procedures

In response to this Notice, any person may file a protest, comments, or a motion to intervene or notice of intervention, as applicable. Interested persons will be provided 20 days from the date of publication of this Notice in which to submit comments, protests, motions to intervene, or notices of intervention. Because the public previously was given an opportunity to intervene in, protest, and comment on Driftwood LNG's pending Application, DOE/FE may disregard comments or protests that do not bear directly on the Supplement—specifically, Driftwood LNG's proposed decrease of its requested non-FTA export volume.

Any person wishing to become a party to the proceeding must file a motion to intervene or notice of intervention. The filing of comments or a protest with respect to the Supplement will not serve to make the commenter or protestant a party to the proceeding, although protests and comments received from persons who are not parties will be considered in determining the appropriate action to be taken on the Application. All protests, comments, motions to intervene, or notices of intervention must meet the requirements specified by the regulations in 10 CFR part 590.

Filings may be submitted using one of the following methods: (1) Emailing the filing to *fergas@hq.doe.gov,* with FE Docket No. 16–144–LNG in the title line; (2) mailing an original and three paper copies of the filing to the Office of Regulation, Analysis, and Engagement at the address listed in **ADDRESSES**; or (3) hand delivering an original and three paper copies of the filing to the Office of Regulation, Analysis, and Engagement at the address listed in **ADDRESSES**. All filings must include a reference to FE Docket No. 16–144–LNG. PLEASE NOTE: If submitting a filing via email, please include all related documents and attachments (*e.g.,* exhibits) in the original email correspondence. Please do not include any active hyperlinks or password protection in any of the documents or attachments related to the filing. All electronic filings submitted to DOE must follow these guidelines to ensure that all documents are filed in a timely manner. Any hardcopy filing submitted greater in length than 50 pages must also include, at the time of the filing, a digital copy on disk of the entire submission.

A decisional record on the Supplement will be developed through responses to this notice by parties, including the parties' written comments and replies thereto. Additional procedures will be used as necessary to achieve a complete understanding of the facts and issues. If an additional procedure is scheduled, notice will be provided to all parties. If no party requests additional procedures, a final Opinion and Order may be issued based on the official record, including the Supplement and responses filed by parties pursuant to this notice, in accordance with 10 CFR 590.316.

The Supplement is available for inspection and copying in the Office of Regulation, Analysis, and Engagement docket room, Room 3E–042, 1000 Independence Avenue SW, Washington, DC 20585. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. The Supplement and any filed protests, motions to intervene or notice of interventions, and comments will also be available electronically by going to the following DOE/FE Web address: *http://www.fe.doe.gov/programs/gasregulation/index.html.*

Signed in Washington, DC, on October 26, 2018.

Amy Sweeney,

Director, Division of Natural Gas Regulation.

[FR Doc. 2018–23867 Filed 10–31–18; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9985–71–OA]

Request for Nominations for a Science Advisory Board Panel To Review the EPA's Draft All-Ages Lead Model (AALM) Software and Model Documents

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) Science Advisory Board (SAB) Staff Office requests public nominations of scientific experts to form a Panel to review EPA's Draft All-Ages Lead Model (AALM) software and model documents. The AALM is a tool for rapidly evaluating the impact of possible sources of lead on blood and other tissue levels in humans from birth to 90 years of age. The AALM predicts lead concentration in body tissues and organs for a hypothetical individual, based on a simulated lifetime of lead exposure.

DATES: Nominations should be submitted by November 23, 2018 per the instructions below.

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing further information regarding this notice and request for nominations may contact Ms. Iris Goodman, 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) 564–2164 or at *goodman.iris@epa.gov.*

General information concerning the EPA SAB can be found at the EPA SAB website at *http://www.epa.gov/sab.*

SUPPLEMENTARY INFORMATION:

Background: The SAB (42 U.S.C. 4365) is a chartered Federal Advisory Committee that provides independent scientific and technical peer review, advice, and recommendations to the EPA Administrator on the technical basis for EPA actions. As a Federal Advisory Committee, the SAB conducts business in accordance with the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2) and related regulations. The SAB AALM Review Panel will provide advice through the chartered SAB on scientific and technical issues related to the current version of the AALM model. The SAB and this Panel will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies.

The U.S. EPA's Office of Research and Development (ORD) in collaboration with Office of Chemical Safety and Pollution Prevention (OCSPP) developed the AALM to provide a tool for rapidly evaluating the impact of possible sources of lead on blood and other tissue levels in humans from birth to 90 years of age. The AALM predicts lead concentration in body tissues and organs for a hypothetical individual, based on a simulated lifetime of lead exposure.

The AALM is an outgrowth of the Integrated Exposure Uptake Biokinetic (IEUBK) Model for Lead in Children. The IEUBK model was designed to assess changes in blood lead of children over periods of no less than a month. The AALM was developed to cover childhood and adult lead exposures and allows users to assess the effects of intermittent lead exposures of a day or more as well as stable exposure conditions.

EPA's ORD and OCSPP coordinated efforts to advance lead biokinetic modeling and produced the current version of the AALM software and documentation. The SAB Staff Office is forming an expert panel under the auspices of the Chartered SAB, the SAB AALM Review Panel, to evaluate the new version of the AALM.

Technical Contact for EPA's draft report: For information concerning EPA's AALM software, and model documents, please contact Dr. James Brown by email at *brown.james@epa.gov* or phone at 919–541–0765.

Request for Nominations: The SAB Staff Office is seeking nominations of nationally and internationally recognized scientists with demonstrated expertise in one or more of the following areas: (1) Physiologically Based Pharmacokinetic modeling, particularly with regard to lead, (2) physiological processes related to lead distribution, mechanisms of transport, accumulation, concentrations at the organ/tissue level, residence times (or other measures of potential impact), and elimination of absorbed lead, (3) processes of the human uptake and/or absorption of ingested lead, (4) lead exposure pathway assessment, and/or (5) environmental or occupational lead exposure analyses.

Process and Deadline for Submitting Nominations: Any interested person or organization may nominate qualified individuals in the areas of expertise described above for possible service on the SAB AALM Review Panel identified in this notice. Nominations should be submitted in electronic format (preferred) following the instructions for ''Nominating Experts to Advisory Panels and Ad Hoc Committees Being Formed,'' provided on the SAB website (see the ''Nomination of Experts'' link under ''Current Activities'' at *http://www.epa.gov/sab.*

To receive full consideration, EPA's SAB Staff Office requests contact information about the person making the nomination; contact information about the nominee; the disciplinary and specific areas of expertise of the nominee; the nominee's resume or curriculum vitae; sources of recent grant and/or contract support; and a biographical sketch of the nominee indicating current position, educational background, research activities, and recent service on other national advisory committees or national professional organizations.

Persons having questions about the nomination procedures, or who are unable to submit nominations through the SAB website, should contact the DFO, Iris Goodman, as indicated above in this notice. Nominations should be submitted in time to arrive no later than November 23, 2018. EPA values and welcomes diversity. All qualified candidates are encouraged to apply regardless of sex, race, disability, or ethnicity.

The EPA SAB Staff Office will acknowledge receipt of nominations. The names and biosketches of qualified nominees identified by respondents to this **Federal Register** notice, and additional experts identified by the SAB Staff Office, will be posted in a List of Candidates for the panel on the SAB website at *http://www.epa.gov/sab.* Public comments on the List of Candidates will be accepted for 21 days. The public will be requested to provide relevant information or other documentation on nominees that the SAB Staff Office should consider in evaluating candidates.

For the EPA SAB Staff Office, a balanced review panel includes candidates who possess the necessary domains of knowledge, the relevant scientific perspectives (which, among other factors, can be influenced by work history and affiliation), and the collective breadth of experience. In forming the expert panel, the SAB Staff Office will consider public comments on the Lists of Candidates, information provided by the candidates themselves, and background information independently gathered by the SAB Staff Office. Selection criteria to be used for panel membership include: (a) Scientific and/or technical expertise, knowledge, and experience (primary factors); (b) availability and willingness to serve; (c) absence of financial conflicts of interest; (d) absence of an appearance of a loss of impartiality; (e) skills working in committees, subcommittees and advisory panels; and (f) for the panel as a whole, diversity of expertise and scientific points of view.

The SAB Staff Office's evaluation of an absence of financial conflicts of interest will include a review of the ''Confidential Financial Disclosure Form for Environmental Protection Agency Special Government Employees'' (EPA Form 3110–48). This confidential form allows government officials to determine whether there is a statutory conflict between a person's public responsibilities (which include membership on an EPA federal advisory committee) and private interests and activities, or the appearance of a loss of impartiality, as defined by federal regulation. The form may be viewed and downloaded from the following URL address *http://yosemite.epa.gov/sab/sabproduct.nsf/Web/ethics?OpenDocument.*

Dated: October 9, 2018.

Khanna Johnston,

Deputy Director, Science Advisory Board Staff Office.

[FR Doc. 2018–23904 Filed 10–31–18; 8:45 am]

BILLING CODE 6560–50–P

FARM CREDIT ADMINISTRATION

Farm Credit Administration Board; Sunshine Act Meetings

AGENCY: Farm Credit Administration.

ACTION: Notice, regular meeting.

SUMMARY: Notice is hereby given, pursuant to the Government in the Sunshine Act, of the regular meeting of the Farm Credit Administration Board (Board).

DATES: The regular meeting of the Board will be held at the offices of the Farm Credit Administration in McLean, Virginia, on November 8, 2018, from 9:00 a.m. until such time as the Board concludes its business.

ADDRESSES: Farm Credit Administration, 1501 Farm Credit Drive, McLean, Virginia 22102–5090. Submit attendance requests via email to *VisitorRequest@FCA.gov.* See **SUPPLEMENTARY INFORMATION** for further information about attendance requests.

FOR FURTHER INFORMATION CONTACT: Dale Aultman, Secretary to the Farm Credit Administration Board, (703) 883–4009, TTY (703) 883–4056, *aultmand@fca.gov.*

SUPPLEMENTARY INFORMATION: This meeting of the Board will be open to the public (limited space available). Please send an email to *VisitorRequest@FCA.gov* at least 24 hours before the meeting. In your email include: Name, postal address, entity you are representing (if applicable), and telephone number. You will receive an email confirmation from us. Please be prepared to show a photo identification when you arrive. If you need assistance for accessibility reasons, or if you have any questions, contact Dale Aultman, Secretary to the Farm Credit Administration Board, at (703) 883–4009. The matters to be considered at the meeting are:

Open Session

A. *Approval of Minutes*

- October 11, 2018

B. *New Business*

- Bookletter BL–070 Revised Capital Treatment for Certain Rural Water and Wastewater Facilities Exposures

Dated: October 30, 2018.

Dale Aultman,

Secretary, Farm Credit Administration Board.

[FR Doc. 2018–24046 Filed 10–30–18; 4:15 pm]

BILLING CODE 6705–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0718]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before December 31, 2018. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0718.

Title: Part 101 Rule Sections Governing the Terrestrial Microwave Fixed Radio Service.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities, not-for-profit institutions, and state, local, or tribal government.

Number of Respondents: 9,500 respondents; 32,446 responses.

Estimated Time per Response: .25–2.85 hours.

Frequency of Response: On occasion and every 10 year reporting requirements, third party disclosure requirement, and recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 151, 154(i), 301, 303(f), 303(g), 303(r), 307, 308, 309, 310, and 316.

Total Annual Burden: 38,290 hours.

Total Annual Cost: $2,564,650.

Privacy Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: The Commission will submit this information collection to the Office of Management and Budget for a three-year approval of OMB Control Number 3060–0718. Part 101 rule sections require respondents to report or disclose information to the Commission or third parties, respectively, and to maintain records. These requirements are necessary for the Commission staff to carry out its duties to determine technical, legal and other qualifications of applicants to operate and remain licensed to operate a station(s) in the common carrier and/or private fixed microwave services. In addition, the information is used to determine whether the public interest, convenience, and necessity are being served as required by 47 U.S.C. 309 and to ensure that applicants and licenses comply with ownership and transfer restrictions imposed by 47 US.C. 310. Without this information, the Commission would not be able to carry out its statutory responsibilities.

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2018–23855 Filed 10–31–18; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Federal Advisory Committee Act; Technological Advisory Council

AGENCY: Federal Communications Commission.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice advises interested persons that the Federal Communications Commission's (FCC) Technological Advisory Council will hold a meeting.

DATES: Wednesday, December 5, 2018 in the Commission Meeting Room, from 10:00 a.m. to 4 p.m.

ADDRESSES: Federal Communications Commission, 445 12th Street SW, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Walter Johnston, Chief, Electromagnetic Compatibility Division, 202–418–0807; *Walter.Johnston@FCC.gov.*

SUPPLEMENTARY INFORMATION: At the December 5th meeting, which is the final meeting of the calendar year, the FCC Technological Advisory Council will discuss recommendations to the FCC Chairman on its work program agreed to at its initial meeting on April 12th, 2018. The FCC will attempt to accommodate as many people as possible. However, admittance will be limited to seating availability. Meetings are also broadcast live with open captioning over the internet from the FCC Live web page at *http://www.fcc.gov/live/.* The public may submit written comments before the meeting to: Walter Johnston, the FCC's Designated Federal Officer for Technological Advisory Council by email: *Walter.Johnston@fcc.gov* or U.S. Postal Service Mail (Walter Johnston, Federal Communications Commission, Room 2–A665, 445 12th Street SW, Washington, DC 20554). Open captioning will be provided for this event. Other reasonable accommodations for people with disabilities are available upon request. Requests for such accommodations should be submitted via email to *fcc504@fcc.gov* or by calling the Office of Engineering and Technology at 202–418–2470 (voice), (202) 418–1944 (fax). Such requests should include a detailed description of the accommodation needed. In addition, please include your contact information. Please allow at least five days advance notice; last minute requests will be accepted, but may not be possible to fill.

Federal Communications Commission.

Ronald T. Repasi,

Deputy Chief, Office of Engineering and Technology.

[FR Doc. 2018–23843 Filed 10–31–18; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0065]

Information Collection Being Submitted for Review and Approval to the Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The Commission may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments should be submitted on or before December 3, 2018. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, OMB, via email *Nicholas_A._Fraser@omb.eop.gov*; and to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Nicole Ongele at (202) 418–2991. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the web page <*http://www.reginfo.gov/public/do/PRAMain*>, (2) look for the section of the web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the OMB control number of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

OMB Control Number: 3060–0065.

Title: Applications for New Authorization or Modification of Existing Authorization Under Part 5 of the FCC Rules-Experimental Radio Service.

Form Number: FCC Form 442.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit; Not-for-profit institutions, Individuals or households, State, Local or Tribal Government.

Number of Respondents and Responses: 405 respondents; 655 responses.

Estimated Time per Response: 15 hours.

Frequency of Response: On occasion reporting requirements; Recordkeeping

requirements; and Third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. Sections 4, 302, 303, 307 and 336 of the Communications Act of 1934, as amended.

Total Annual Burden: 3,474 hours.

Total Annual Cost: $52,150.

Privacy Act Impact Assessment: This information collection affects individuals or households. The Commission has a System of Records, FCC/OET–1 ''Experimental Radio Station License Files'' which covers the personally identifiable information (PII) that individual applicants may include in their submissions for experimental radio authorizations. The system of records notice (SORN) was published in the **Federal Register** on April 5, 2006, *see* 71 FR 17234, 17241. The SORN may be viewed at *https://www.fcc.gov/general/privacy-act-information.*

Nature and Extent of Confidentiality: Applicants may request that any information supplied be withheld from public inspection, *e.g.,* granted confidentiality, pursuant to 47 CFR Section 0.459 of the Commission's rules.

Needs and Uses: The Commission will submit this revised information collection to the Office of Management and Budget (OMB) after this 60-day comment period to obtain the three-year clearance.

On June 29, 2016, the Commission adopted a Second Report and Order, in ET Docket No. 10–236 and 06–155; FCC 16–86, which updates Part 5 of the CFR—''Experimental Radio Service'' (ERS).[1] The Commission's recent Report and Order revises and streamlines the rule part under for the ERS. This rule change allows licensees operation under frequency bands mentioned in Section 5.303 and as state, within rule part 15.205(a). These rule changes update procedures used to obtain and use an experimental license.

§ 5.303 Frequencies.

(a) Licensees may operate in any frequency band, including those above 38.6 GHz, except for frequency bands exclusively allocated to the passive services (including the radio astronomy service). In addition, licensees may not use any frequency or frequency band below 38.6 GHz that is listed in § 15.205(a) of this chapter.

(b) *Exception:* Licensees may use frequencies listed in § 15.205(a) of this chapter for testing medical devices (as defined in § 5.402(b) of this chapter), if the device is designed to comply with all applicable service rules in Part 18, Industrial, Scientific, and Medical Equipment; Part 95, Personal Radio Services Subpart H—Wireless Medical Telemetry Service; or Part 95, Subpart I—Medical Device Radiocommunication Service.

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2018–23853 Filed 10–31–18; 8:45 am]

BILLING CODE 6712–01–P

[1] *See* In the Matter of Promoting Expanded Opportunities for Radio Experimentation and Market Trials Under Part 5 of the Commission's Rules and Streamlining Other Related Rules, ET Docket No. 10–236; 2006 Biennial Review of Telecommunications Regulations—Part 2, Administered by the Office of Engineering and Technology (OET), ET Docket No. 06–155; 31 FCC Rcd 7529 (2016), FCC 16–86.

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0669]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before December 31, 2018. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0669.

Title: Section 76.946, Advertising of Rates.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business and other for-profit entities.

Number of Respondents and Responses: 8,250 respondents; 8,250 responses.

Estimated Time per Response: 30 minutes (0.5 hours).

Frequency of Response: On occasion reporting requirement; Third party disclosure requirement.

Total Annual Burden to Respondents: 4,125 hours.

Total Annual Costs: None.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in Section 4(i) of the Communications Act of 1934, as amended.

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Privacy Impact Assessment: No impact(s).

Needs and Uses: The information collection requirements contained in 47 CFR 76.946 states that cable operators that advertise rates for basic service and cable programming service tiers shall be required to advertise rates that include all costs and fees. Cable systems that cover multiple franchise areas having differing franchise fees or other franchise costs, different channel line-ups, or different rate structures may advertise a complete range of fees without specific identification of the rate for each individual area. In such circumstances, the operator may advertise a ''fee plus'' rate that indicates the core rate plus the range of possible additions, depending on the particular location of the subscriber.

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2018–23845 Filed 10–31–18; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL LABOR RELATIONS AUTHORITY

Senior Executive Service Performance Review Board

AGENCY: Federal Labor Relations Authority.

ACTION: Notice.

SUMMARY: The Federal Labor Relations Authority (FLRA) publishes the names of the persons selected to serve on its SES Performance Review Board (PRB). This notice supersedes all previous notices of the PRB membership.

DATES: Upon publication.

ADDRESSES: Written comments about this final rule can be mailed to the Case Intake and Publication Office, Federal Labor Relations Authority, 1400 K Street NW, Washington, DC 20424. All written comments will be available for public inspection during normal business hours at the Case Intake and Publication Office.

FOR FURTHER INFORMATION CONTACT: William Tosick, Executive Director, Federal Labor Relations Authority, 1400 K St. NW, Washington, DC 20424, (202) 218–7791, *wtosick@flra.gov.*

SUPPLEMENTARY INFORMATION: Section 4314(c) of Title 5, U.S.C. requires each agency to establish, in accordance with regulations prescribed by the Office of Personnel Management, one or more PRBs. The PRB shall review and evaluate the initial appraisal of a senior executive's performance by the supervisor, along with any response by the senior executive, and make recommendations to the final rating authority relative to the performance of the senior executive.

The persons named below have been selected to serve on the FLRA's PRB.

PRB Chairman:

William Tosick, Executive Director

PRB Members:

Kimberly D. Moseley, Executive Director, Federal Service Impasses Panel; Douglas Fitzgerald, Director, Division of Longshore and Harbor Workers' Compensation at U.S. Department of Labor; Richard Jones, Atlanta Regional Director; and Paula Chandler, Director, Human Resources Division, FLRA, as an ex officio member.

Dated: October 29, 2018.

William Tosick,

Executive Director.

[FR Doc. 2018–23898 Filed 10–31–18; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–19–0969]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''Monitoring Changes in Attitudes and Practices among Family Planning Providers and Clinics'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on June 8, 2018 to obtain comments from the public and affected agencies. CDC received one substantive and five non-substantive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) 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;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) 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; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Monitoring Changes in Attitudes and Practices among Family Planning Providers and Clinics (OMB Number 0920–0969, Expiration Date: 05/31/2014)—Reinstatement with Change—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Division of Reproductive Health (DRH) at the Centers for Disease Control and Prevention (CDC) and the HHS Office of Population Affairs (OPA) develop and disseminate guidance to improve the use of contraception and the delivery of quality family planning services. The *U.S. Medical Eligibility Criteria for Contraceptive Use* (US MEC), the first national guidance on family planning containing evidence-based recommendations for the safe use of contraceptive methods for women and men with specific characteristics and medical conditions, was first published by the CDC in June 2010. The *US Selected Practice Recommendations for Contraceptive Use* (US SPR), which provides guidance on how to use contraceptive methods safely and effectively once they are deemed to be medically appropriate, was first published by the CDC in June 2013. The US MEC and US SPR were updated after review of the scientific evidence and consultation with national experts in family planning; the revised US MEC and US SPR were published in August 2016.

Providing Quality Family Planning Services (QFP), which provides evidence-informed recommendations to improve client care and service delivery infrastructure to support the provision of quality family planning services to women and men of reproductive age in the United States, was published by CDC and OPA in April 2014. The US MEC, US SPR, and QFP have been widely disseminated to health care providers and other constituents via professional organizations, federal program grantees, scientific and programmatic meetings, scientific

manuscripts, online resources, and other avenues.

To monitor changes in attitudes and practices regarding provision of contraception among family planning providers and clinics, we initiated a multi-phase assessment. In 2009–2010, CDC carried out the first phase of the assessment, collecting information before the release of the US MEC (OMB No. 0920–0008). In 2013–2014, CDC, in collaboration with OPA, carried out the second phase of the assessment, collecting information before the release of the US SPR and QFP (OMB No. 0920–0969). These information collections provided useful knowledge about attitudes and practices of family planning providers. CDC and OPA used the findings to develop educational materials and opportunities for health care providers.

In 2018, in collaboration with OPA, CDC plans to request a reinstatement of OMB No. 0920–0969, 'Monitoring Changes in Attitudes and Practices among Family Planning Providers and Clinics' to carry out the third phase of the assessment. As in the previous phases, the information collection will allow CDC and OPA to improve family planning-related practice by: (1) Understanding the current use of contraception guidance in practice, including awareness and use of the US MEC, US SPR and QFP; (2) describing current attitudes and practices among family planning providers and clinics related to recommendations included in the US MEC, US SPR, and QFP and assessing changes from previous data collections; and (3) identifying training needs in use of guidance and family planning service delivery (*e.g.,* provider tools, continuing education modules).

As in previous phases of data collection, CDC plans to administer surveys to private and public sector family planning providers and clinic administrators in the United States. The design, methodology, and analytic approach that CDC plans to implement are based on methods previously approved for the 2013–2014 survey, with different instruments being administered to providers and clinic administrators. Minor changes to survey content will be made to eliminate unnecessary questions, add new questions of interest, and improve formatting, usability, and data quality. The estimated burden per response for providers is 15 minutes and has not changed since the previous OMB approval. The estimated burden per response for administrators will be reduced from 40 minutes to 35 minutes. The total burden for participants is estimated at 1,916 hours. Participation is voluntary and there are no costs to respondents other than their time. OMB approval is requested for one year.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Office-based physicians (private sector)	2018–2019 Survey of Health Care Providers about Family Planning Attitudes and Practices.	1,000	1	15/60
Title X clinic providers (public sector)	2018–2019 Survey of Health Care Providers about Family Planning Attitudes and Practices.	1,000	1	15/60
Non-Title X clinic providers (public sector)	2018–2019 Survey of Health Care Providers about Family Planning Attitudes and Practices.	1,000	1	15/60
Title X clinic administrators (public sector)	2018–2019 Survey of Administrators of Health Centers that Provide Family Planning.	1,000	1	35/60
Non-Title X clinic administrators (public sector).	2018–2019 Survey of Administrators of Health Centers that Provide Family Planning.	1,000	1	35/60

Jeffrey M. Zirger,

Acting Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2018–23862 Filed 10–31–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-19–0488]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Report of Illness or Death: Interstate Travel of Persons (42 CFR part 70) to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on August 21, 2018 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) 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;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) 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; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Report of Illness or Death: Interstate Travel of Persons (42 CFR part 70)—Revision—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 361 of the Public Health Service Act (42 U.S.C. 264) authorizes the Secretary of the Department of Health and Human Services to make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States, or from one State or possession into any other State or possession. CDC administers regulations pertaining to interstate control of communicable diseases (42 CFR part 70), and sections 42 CFR parts 70.4 and 70.11 include requirements for reports of ill persons or death if occurring during interstate travel.

The intended use of the information is to ensure that CDC can assess and respond to reports of ill persons or death that occur on conveyances engaged in interstate travel, and assist state and local health authorities if an illness or death occurs that poses a risk to public health. Generally, the primary source of this information is aircraft traveling within the United States.

In 2017, CDC finalized the Control of Communicable Disease regulations (42 CFR 70 and 71). With this new provision, CDC divided the total anticipated reporting burden between 70.11 and 70.4 in the accompanying Paperwork Reduction Act section of the rule, assuming that aircraft would report most cases of ill people and deaths to CDC, with some airlines and other conveyances reporting still to local public health authorities. For reports of ill persons or death on a conveyance engaged in interstate traffic, the requested burden is approximately 23 hours. This total is estimated from 200 respondents submitting domestic reports of death or communicable disease a year, with an average burden of 7 minutes per report. The only requested change to the approved data collection is a change in title from ''Restriction on Travel of Persons (42 CFR part 70)'' to ''Report of Illness or Death: Interstate Travel of Persons (42 CFR part 70)''. This results in two rows in the burden table, but with no additional burden. The estimated annual Burden Hours are 23. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Pilot in command	42 CFR 70.11 Report of death or illness onboard aircraft operated by airline.	190	1	7/60
Master of vessel or person in charge of conveyance.	42 CFR 70.4 Report by the master of a vessel or person in charge of conveyance of the incidence of a communicable disease occurring while in interstate travel.	10	1	7/60

Jeffrey M. Zirger

Acting Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2018–23861 Filed 10–31–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0873]

Agency Information Collection Activities; Proposed Collection; Comment Request; Bar Code Label Requirement for Human Drug and Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on bar code label requirements for human drug and biological products.

DATES: Submit either electronic or written comments on the collection of information by December 31, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 31, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 31, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2012–N–0873 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Bar Code Label Requirement for Human Drug and Biological Products.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St, North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Bar Code Label Requirement for Human Drug and Biological Products

OMB Control Number 0910–0537—Extension

In the **Federal Register** of February 26, 2004 (69 FR 9120), FDA issued a final rule that requires human drug product and biological product labels to have bar codes. Specifically, the final rule requires bar codes on most human prescription drug products and on over-the-counter (OTC) drug products that are dispensed under an order and commonly used in health care facilities. It also requires machine-readable information on blood and blood components. For human prescription drug products and OTC drug products that are dispensed under an order and commonly used in health care facilities, the bar code must contain the national drug code number for the product. For blood and blood components, the final rule specifies the minimum contents of the label in a format that is machine readable and approved for use by the Director, Center for Biologics Evaluation and Research. We believe that the final rule helps reduce the number of medication errors in hospitals and other health care settings by allowing health care professionals to use bar code scanning equipment to verify that the right drug (in the right dose and right route of administration) is being given to the right patient at the right time.

Although most of the information collections created by the final rule have now been incorporated in OMB approved information collections supporting the applicable regulations, respondents to the collection may continue to seek an exemption from the bar code label requirement under § 201.25(d) (21 CFR 201.25(d)). Section 201.25(d) requires submission of a written request for an exemption and describes the information that must be included in such a request. Based on the number of exemption requests we have received previously, we estimate that approximately 2 exemption requests will be submitted annually and each exemption request will require 24 hours to complete. This results in an annual reporting burden of 48 hours, as reflected in table 1.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
21 CFR 201.25(d)	2	1	2	24	48

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: October 29, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–23910 Filed 10–31–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel Review of NIEHS K08, K23, K24, and K25 Applications.

Date: November 13, 2018.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Science, Keystone Building, 530 Davis Drive, Room 2164, Research Triangle Park, NC 27709 (Telephone Conference Call).

Contact Person: Janice B. Allen, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, National Institute of Environmental Health Science, 530 Davis Drive, Room 3170 B, Research Triangle Park, NC 27709, (919) 541–7556, *allen9@niehs.nih.gov*.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel Review of NIEHS Revolutionizing Innovative, Visionary Environmental Health Research (RIVER) APPLICATIONS.

Date: November 15, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Marriott Chapel Hill, 01 Erwin Road, Chapel Hill, NC 27514.

Contact Person: Leroy Worth, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, National Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–30/Room 3171, Research Triangle Park, NC 27709, 919/541–0670, *worth@niehs.nih.gov*.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel NIH/NIEHS E-Learning for HAZMAT and Emergency Response.

Date: November 19, 2018.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: NIEHS/National Institutes of Health Keystone Building, 530 Davis Drive, Room 2164, Research Triangle Park, NC 27709 (Telephone Conference Call).

Contact Person: Laura A. Thomas, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, National Institute of Environmental Health Sciences, Research Triangle Park, NC 27709, 919–541–2824, *laura.thomas@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: October 26, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–23856 Filed 10–31–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Shared Instrumentation: Interdisciplinary Molecular Sciences and Technologies (S10).

Date: November 27, 2018.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Alexander Gubin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6046B, MSC 7892, Bethesda, MD 20892, 301–408–9655, *gubina@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Nephrology Small Business Review.

Date: November 27, 2018.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Atul Sahai, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2188, MSC 7818, Bethesda, MD 20892, 301–435–1198, *sahaia@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Chemosensory Systems, Neurotoxicology and Alcohol.

Date: November 27, 2018.

Time: 3:00 p.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).
Contact Person: M. Catherine Bennett, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5182, MSC 7846, Bethesda, MD 20892, 301–435–1766, *bennettc3@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 26, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–23848 Filed 10–31–18; 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, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; PHS–2017–1 Phase II Topic 43.
Date: November 27, 2018.
Time: 10:00 a.m. to 12:00 p.m.
Agenda: To review and evaluate contract proposals.
Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).
Contact Person: Priti Mehrotra, Ph.D., Chief, Immunology Review Branch, Scientific Review Program, Division of Extramural Activities, Room #3G40, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–7616, 240–669–5066, *pmehrotra@niaid.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: October 26, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–23846 Filed 10–31–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: AIDS and Related Research.
Date: November 30, 2018.
Time: 9:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Shalanda A. Bynum, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3206, Bethesda, MD 20892, 301–755–4355, *bynumsa@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business, Musculoskeletal Rehabilitation Sciences.
Date: November 30, 2018.
Time: 10:00 a.m. to 4:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.
Contact Person: Maria Nurminskaya, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, Bethesda, MD 20892, (301) 435–1222, *nurminskayam@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: U.S. Tobacco Control Policies to Reduce Health Disparities.
Date: November 30, 2018.
Time: 10:30 a.m. to 12:30 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).
Contact Person: Kristen Prentice, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3112, MSC 7808, Bethesda, MD 20892, 301–496–0726, *prenticekj@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Review: Cancer Behavioral Research with Existing Data and Communication in the New Media.
Date: November 30, 2018.
Time: 11:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).
Contact Person: John H. Newman, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3222, MSC 7808, Bethesda, MD 20892, (301) 435–0628, *newmanjh@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Large Animal Testing Centers for Evaluation of Somatic Cell Genome Editing Tools (U42).
Date: November 30, 2018.
Time: 12:00 p.m. to 7:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).
Contact Person: Natalia Komissarova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5207, MSC 7846, Bethesda, MD 20892, 301–435–1206, *komissar@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 26, 2018.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–23847 Filed 10–31–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a

meeting of the Board of Scientific Counselors, NICHD.

The meeting will be open to the public as indicated below, with the 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 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 EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT, 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, NICHD.

Date: December 7, 2018.

Open: 8:00 a.m. to 11:30 a.m.

Agenda: A report by the Scientific Director, NICHD, on the status of the NICHD Division of Intramural Research; talks by various intramural scientists, and current organizational structure.

Place: National Institutes of Health, Building 31A, Conference Room 2A48, 31 Center Drive, Bethesda, MD 20892.

Closed: 11:30 a.m. to 4:00 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 31A, Conference Room 2A48, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Constantine A. Stratakis, MD, D(med)Sci Scientific Director, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, Building 31A, Room 2A46, 31 Center Drive, Bethesda, MD 20892, 301–594–5984, *stratakc@mail.nih.gov*.

Information is also available on the Institute's/Center's home page: *https://www.nichd.nih.gov/about/meetings/Pages/index.aspx,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: October 26, 2018.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–23857 Filed 10–31–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Senior Executive Service Performance Review Board; Correction

AGENCY: Office of the Secretary, Department of Homeland Security.

ACTION: Notice; correction.

SUMMARY: The Department of Homeland Security (DHS) published the members of the FY 2018 Senior Executive Service (SES) Performance Review Board (PRB) in the **Federal Register** on October 9, 2018. This notice correction is adding five additional names to the previously published PRB list.

DATES: This Notice is current as of November 1, 2018.

FOR FURTHER INFORMATION CONTACT: Julie Hart, Office of the Chief Human Capital Officer, Julie.Hart@hq,dhs.gov, or by telephone (202) 357–8123.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of October 9, 2018, in FR Doc. 2018–21887, on page 50674 and page 50675, the following five names have been added to the list that make up the composition of the PRBS:

Hentz, Andre
Lim, Marie Evelyn
Quinn, Cameron
Taylor, Miles
Wolf, Chad

Dated: October 25, 2018.

Greg Ruocco,

Manager, Executive Resources Policy, Office of the Chief Human Capital Officer.

[FR Doc. 2018–23903 Filed 10–31–18; 8:45 am]

BILLING CODE 9110–9B–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Immigration and Customs Enforcement

[1653–0054]

Agency Information Collection Activities; Extension, With Changes, of an Existing Information Collection: Training Plan for Science, Technology, Engineering and Mathematics (STEM) Optional Practical Training (OPT) Students

ACTION: 60-Day notice.

The Department of Homeland Security, U.S. Immigration and Customs Enforcement (USICE), is submitting the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until December 31, 2018.

Written comments and suggestions regarding items contained in this notice and especially with regard to the estimated public burden and associated response time should be directed to the PRA Clearance Officer for USICE and sent via electronic mail to *icepra@ice.dhs.gov.*

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies' estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension, with changes, of a currently approved information collection.

(2) *Title of the Form/Collection:* Training Plan for STEM OPT Students.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I–983, U.S. Immigration and Customs Enforcement.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or households. The Form I–983 serves as a planning document for STEM OPT students, the SEVP-certified school, and the employer. The Training Plan for STEM OPT Students also serves as an evidentiary document for SEVP, by tracking the STEM OPT student's progress, setting forth the terms and conditions of the practical training, and documenting the obligations of the three parties that are involved—the F student, the SEVP-certified school, and the employer.

The student and the employer must each complete and sign their part of the Form I–983. The SEVP certified school will incorporate the completed and signed Form I–983, as part of the student's school file. The SEVP-certified school will make the student's Form I–983 available to DHS upon request.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:

TABLE 1—CALCULATION OF ANNUAL REPORTING BURDEN FOR TRAINING PLAN

Function	Avg annual responses	Time per response (hours)	Avg annual hour burden
Student Burden			
Initial Completion of Training Plan	166,406	2.17	361,101
12-month Evaluation Requirements	166,406	1.50	249,609
Sub-Total			610,710
DSO Burden			
Initial Review of Training Plan & Recordkeeping	166,406	1.33	221,320
Review of Evaluation & Recordkeeping	166,406	1.33	221,320
Sub-Total			442,640
Employer Burden			
Initial completion of Training Plan	166,406	4.00	665,624
Evaluation Requirements	166,406	0.75	124,805
Sub-Total			790,429
Total Burden Hours			1,843,779

(6) An estimate of the total public burden (in hours) associated with the collection: 1,843,779 annual burden hours.

Dated: October 29, 2018.

Scott Elmore,

PRA Clearance Officer, Office of the Chief Information Officer, U.S. Immigration and Customs Enforcement, Department of Homeland Security.

[FR Doc. 2018–23907 Filed 10–31–18; 8:45 am]

BILLING CODE 9111–28–P

DEPARTMENT OF HOMELAND SECURITY

United States Immigration and Customs Enforcement

[1653–0037]

Agency Information Collection Activities; Extension, Without Change, of an Existing Information Collection: Notice to Student or Exchange Visitor

AGENCY: U.S. Immigration and Customs Enforcement, Department of Homeland Security.

ACTION: 60-Day notice.

SUMMARY: The Department of Homeland Security, U.S. Immigration and Customs Enforcement (USICE), is submitting the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and will be accepted for sixty days until December 31, 2018.

ADDRESSES: Written comments and suggestions regarding items contained in this notice and especially with regard to the estimated public burden and associated response time should be directed to the Department of Homeland Security (DHS), Scott Elmore, Forms Management Office, U.S. Immigrations and Customs Enforcement, 801 I Street NW, Mailstop 5800, Washington, DC 20536–5800.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies' estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension, without change, of a currently approved information collection.

(2) *Title of the Form/Collection:* Notice to Student or Exchange Visitor.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I–515A; U.S. Immigration and Customs Enforcement.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or Households. An academic nonimmigrant student (F–1), vocational nonimmigrant student (M–1), exchange visitor (J–1), or dependent (F–2, M–2 or J–2) seeking admission into the United States as a nonimmigrant under section 101(a)(15) of the Immigration and Nationality Act (Act) is required to present certain documentation at the port of entry. If the F, J or M nonimmigrant is missing any piece of this documentation, a Department of Homeland Security (DHS) Customs and Border Protection (CBP) officer at the port of entry has discretion to issue the F, J or M nonimmigrant a Form I–515A, Notice to Student or Exchange Visitor, which allows the nonimmigrant temporary entry into the United States for 30 days in order for the nonimmigrant to compile and submit the documentation. The Form I–515A provides a list of the documentation the F, J or M nonimmigrant will need to provide to DHS. The F, J or M nonimmigrant must send the documentation to the Student and Exchange Visitor Program (SEVP), an office of the DHS agency, U.S. Immigration and Customs Enforcement (ICE). SEVP must receive a complete response within 30 days of the F, J or M nonimmigrant's admission. Form I–515A collects information authorized by 8 U.S.C. 1101 and 1184 to confirm that the F, J or M nonimmigrant is eligible for admission into the United States. The Form I–515A enables CBP to avoid having to deny entry into the United States to an otherwise eligible F, J or M nonimmigrant.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 4,744 responses at 10 minutes (0.166 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 788 annual burden hours.

Dated: October 29, 2018.

Scott Elmore,

Program Manager, Forms Management Office, Office of the Chief Information Officer, U.S. Immigration and Customs Enforcement, Department of Homeland Security.

[FR Doc. 2018–23906 Filed 10–31–18; 8:45 am]

BILLING CODE 9111–28–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–447 and 731–TA–1116 (Second Review)]

Circular Welded Carbon-Quality Steel Pipe From China; Institution of Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice that it has instituted reviews pursuant to the Tariff Act of 1930 (''the Act''), as amended, to determine whether revocation of the antidumping and countervailing duty orders on circular welded carbon-quality steel pipe from China would be likely to lead to continuation or recurrence of material injury. Pursuant to the Act, interested parties are requested to respond to this notice by submitting the information specified below to the Commission.

DATES: Instituted November 1, 2018. To be assured of consideration, the deadline for responses is December 3, 2018. Comments on the adequacy of responses may be filed with the Commission by January 14, 2019.

FOR FURTHER INFORMATION CONTACT: Mary Messer (202–205–3193), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server *https://www.usitc.gov.* The public record for this proceeding may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On July 22, 2008, the Department of Commerce (''Commerce'') issued antidumping and countervailing duty orders on imports of circular welded carbon-quality steel pipe from China (73 FR 42545–42549). Following the first five-year reviews by Commerce and the Commission, effective December 4, 2013, Commerce issued a continuation of the antidumping and countervailing duty orders on imports of circular welded carbon-quality steel pipe from China (78 FR 72863). The Commission is now conducting second reviews pursuant to section 751(c) of the Act, as amended (19 U.S.C. 1675(c)), to determine whether revocation of the orders would be likely to lead to continuation or recurrence of material injury to the domestic industry within a reasonably foreseeable time. Provisions concerning the conduct of this proceeding may be found in the Commission's Rules of Practice and Procedure at 19 CFR parts 201, subparts A and B and 19 CFR part 207, subparts A and F. The Commission will assess the adequacy of interested party responses to this notice of institution to determine whether to conduct full or expedited reviews. The Commission's determinations in any expedited reviews will be based on the facts available, which may include information provided in response to this notice.

Definitions.—The following definitions apply to these reviews:

(1) *Subject Merchandise* is the class or kind of merchandise that is within the scope of the five-year reviews, as defined by the Department of Commerce.

(2) The *Subject Country* in these reviews is China.

(3) The *Domestic Like Product* is the domestically produced product or products which are like, or in the absence of like, most similar in characteristics and uses with, the *Subject Merchandise.* In its original determinations and its expedited first five-year review determinations, the Commission defined the *Domestic Like Product* as circular welded carbon quality steel line pipe, 16 inches or less in outside diameter, coextensive with Commerce's scope.

(4) The *Domestic Industry* is the U.S. producers as a whole of the *Domestic Like Product,* or those producers whose collective output of the *Domestic Like Product* constitutes a major proportion of the total domestic production of the product. In its original determinations and its first five-year review determinations, the Commission defined the *Domestic Industry* as all producers of the *Domestic Like Product.*

(5) An *Importer* is any person or firm engaged, either directly or through a parent company or subsidiary, in importing the *Subject Merchandise* into the United States from a foreign manufacturer or through its selling agent.

Participation in the proceeding and public service list.—Persons, including industrial users of the *Subject Merchandise* and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the proceeding as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11(b)(4) of the Commission's rules, no later than 21 days after publication of this notice in the **Federal Register.** The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the proceeding.

Former Commission employees who are seeking to appear in Commission five-year reviews are advised that they may appear in a review even if they participated personally and substantially in the corresponding underlying original investigation or an earlier review of the same underlying investigation. The Commission's designated agency ethics official has advised that a five-year review is not the same particular matter as the underlying original investigation, and a five-year review is not the same particular matter as an earlier review of the same underlying investigation for purposes of 18 U.S.C. 207, the post employment statute for Federal employees, and Commission rule 201.15(b) (19 CFR 201.15(b)), 79 FR 3246 (Jan. 17, 2014), 73 FR 24609 (May 5, 2008). Consequently, former employees are not required to seek Commission approval to appear in a review under Commission rule 19 CFR 201.15, even if the corresponding underlying original investigation or an earlier review of the same underlying investigation was pending when they were Commission employees. For further ethics advice on this matter, contact Charles Smith, Office of the General Counsel, at 202–205–3408.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and APO service list.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI submitted in this proceeding available to authorized applicants under the APO issued in the proceeding, provided that the application is made no later than 21 days after publication of this notice in the **Federal Register.** Authorized applicants must represent interested parties, as defined in 19 U.S.C. 1677(9), who are parties to the proceeding. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Certification.—Pursuant to section 207.3 of the Commission's rules, any person submitting information to the Commission in connection with this proceeding must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will acknowledge that information submitted in response to this request for information and throughout this proceeding or other proceeding may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

Written submissions.—Pursuant to section 207.61 of the Commission's rules, each interested party response to this notice must provide the information specified below. The deadline for filing such responses is December 3, 2018. Pursuant to section 207.62(b) of the Commission's rules, eligible parties (as specified in Commission rule 207.62(b)(1)) may also file comments concerning the adequacy of responses to the notice of institution and whether the Commission should conduct expedited or full reviews. The deadline for filing such comments is January 14, 2019. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's Handbook on E-Filing, available on the Commission's website at *https://edis.usitc.gov,* elaborates upon the Commission's rules with respect to electronic filing. Also, in accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the proceeding must be served on all other parties to the proceeding (as identified by either the public or APO service list as appropriate), and a certificate of service must accompany the document (if you are not a party to the proceeding you do not need to serve your response).

No response to this request for information is required if a currently valid Office of Management and Budget (''OMB'') number is not displayed; the OMB number is 3117 0016/USITC No. 18–5–414, expiration date June 30, 2020. Public reporting burden for the request is estimated to average 15 hours per response. Please send comments regarding the accuracy of this burden estimate to the Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436.

Inability to provide requested information.—Pursuant to section 207.61(c) of the Commission's rules, any interested party that cannot furnish the information requested by this notice in the requested form and manner shall notify the Commission at the earliest possible time, provide a full explanation of why it cannot provide the requested information, and indicate alternative forms in which it can provide equivalent information. If an interested party does not provide this notification (or the Commission finds the explanation provided in the notification inadequate) and fails to provide a complete response to this notice, the Commission may take an adverse inference against the party pursuant to section 776(b) of the Act (19 U.S.C. 1677e(b)) in making its determinations in the reviews.

Information To Be Provided in Response to This Notice of Institution: As used below, the term ''firm'' includes any related firms.

(1) The name and address of your firm or entity (including World Wide Web address) and name, telephone number, fax number, and Email address of the certifying official.

(2) A statement indicating whether your firm/entity is an interested party under 19 U.S.C. 1677(9) and if so, how, including whether your firm/entity is a U.S. producer of the *Domestic Like Product,* a U.S. union or worker group, a U.S. importer of the *Subject Merchandi*se, a foreign producer or exporter of the *Subject Merchandise,* a U.S. or foreign trade or business association (a majority of whose

members are interested parties under the statute), or another interested party (including an explanation). If you are a union/worker group or trade/business association, identify the firms in which your workers are employed or which are members of your association.

(3) A statement indicating whether your firm/entity is willing to participate in this proceeding by providing information requested by the Commission.

(4) A statement of the likely effects of the revocation of the antidumping and countervailing duty orders on the *Domestic Industry* in general and/or your firm/entity specifically. In your response, please discuss the various factors specified in section 752(a) of the Act (19 U.S.C. 1675a(a)) including the likely volume of subject imports, likely price effects of subject imports, and likely impact of imports of *Subject Merchandise* on the *Domestic Industry.*

(5) A list of all known and currently operating U.S. producers of the *Domestic Like Product.* Identify any known related parties and the nature of the relationship as defined in section 771(4)(B) of the Act (19 U.S.C. 1677(4)(B)).

(6) A list of all known and currently operating U.S. importers of the *Subject Merchandise* and producers of the *Subject Merchandise* in the *Subject Country* that currently export or have exported *Subject Merchandise* to the United States or other countries after 2012.

(7) A list of 3–5 leading purchasers in the U.S. market for the *Domestic Like Product* and the *Subject Merchandise* (including street address, World Wide Web address, and the name, telephone number, fax number, and Email address of a responsible official at each firm).

(8) A list of known sources of information on national or regional prices for the *Domestic Like Product* or the *Subject Merchandise* in the U.S. or other markets.

(9) If you are a U.S. producer of the *Domestic Like Product,* provide the following information on your firm's operations on that product during calendar year 2017, except as noted (report quantity data in short tons and value data in U.S. dollars, f.o.b. plant). If you are a union/worker group or trade/business association, provide the information, on an aggregate basis, for the firms in which your workers are employed/which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total U.S. production of the *Domestic Like Product* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm to produce the *Domestic Like Product* (that is, the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix);

(c) the quantity and value of U.S. commercial shipments of the *Domestic Like Product* produced in your U.S. plant(s);

(d) the quantity and value of U.S. internal consumption/company transfers of the *Domestic Like Product* produced in your U.S. plant(s); and

(e) the value of (i) net sales, (ii) cost of goods sold (COGS), (iii) gross profit, (iv) selling, general and administrative (SG&A) expenses, and (v) operating income of the *Domestic Like Product* produced in your U.S. plant(s) (include both U.S. and export commercial sales, internal consumption, and company transfers) for your most recently completed fiscal year (identify the date on which your fiscal year ends).

(10) If you are a U.S. importer or a trade/business association of U.S. importers of the *Subject Merchandise* from the *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2017 (report quantity data in short tons and value data in U.S. dollars). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) The quantity and value (landed, duty-paid but not including antidumping or countervailing duties) of U.S. imports and, if known, an estimate of the percentage of total U.S. imports of *Subject Merchandise* from the *Subject Country* accounted for by your firm's(s') imports;

(b) the quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. commercial shipments of *Subject Merchandise* imported from the *Subject Country;* and

(c) the quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. internal consumption/company transfers of *Subject Merchandise* imported from the *Subject Country.*

(11) If you are a producer, an exporter, or a trade/business association of producers or exporters of the *Subject Merchandise* in the *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2017 (report quantity data in short tons and value data in U.S. dollars, landed and duty-paid at the U.S. port but not including antidumping or countervailing duties). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total production of *Subject Merchandise* in the *Subject Country* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm(s) to produce the *Subject Merchandise* in the *Subject Country* (that is, the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix); and

(c) the quantity and value of your firm's(s') exports to the United States of *Subject Merchandise* and, if known, an estimate of the percentage of total exports to the United States of *Subject Merchandise* from the *Subject Country* accounted for by your firm's(s') exports.

(12) Identify significant changes, if any, in the supply and demand conditions or business cycle for the *Domestic Like Product* that have occurred in the United States or in the market for the *Subject Merchandise* in the *Subject Country* after 2012, and significant changes, if any, that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the *Domestic Like Product* produced in the United States, *Subject Merchandise* produced in the *Subject Country,* and such merchandise from other countries.

(13) (OPTIONAL) A statement of whether you agree with the above definitions of the *Domestic Like Product* and *Domestic Industry;* if you disagree

with either or both of these definitions, please explain why and provide alternative definitions.

Authority: This proceeding is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.61 of the Commission's rules.

By order of the Commission.

Issued: October 26, 2018.

Katherine Hiner,

Supervisory Attorney.

[FR Doc. 2018–23851 Filed 10–31–18; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–909 (Third Review)]

Low Enriched Uranium From France; Institution of a Five-Year Review

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice that it has instituted a review pursuant to the Tariff Act of 1930 (''the Act''), as amended, to determine whether revocation of the antidumping duty order on low enriched uranium from France would be likely to lead to continuation or recurrence of material injury. Pursuant to the Act, interested parties are requested to respond to this notice by submitting the information specified below to the Commission.

DATES: Instituted November 1, 2018. To be assured of consideration, the deadline for responses is December 3, 2018. Comments on the adequacy of responses may be filed with the Commission by January 14, 2019.

FOR FURTHER INFORMATION CONTACT: Mary Messer (202–205–3193), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server *https://www.usitc.gov*. The public record for this proceeding may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On February 13, 2002, the Department of Commerce issued an antidumping duty order on imports of low enriched uranium from France (67 FR 6680). Following the five-year reviews by Commerce and the Commission, effective January 3, 2008, Commerce issued a continuation of the antidumping duty order on imports of low enriched uranium from France (73 FR 449). Following the second five-year reviews by Commerce and the Commission, effective December 24, 2013, Commerce issued a continuation of the antidumping duty order on imports of low enriched uranium from France (78 FR 77650). The Commission is now conducting a third five-year review pursuant to section 751(c) of the Act, as amended (19 U.S.C. 1675(c)), to determine whether revocation of the order would be likely to lead to continuation or recurrence of material injury to the domestic industry within a reasonably foreseeable time. Provisions concerning the conduct of this proceeding may be found in the Commission's Rules of Practice and Procedure at 19 CFR parts 201, subparts A and B and 19 CFR part 207, subparts A and F. The Commission will assess the adequacy of interested party responses to this notice of institution to determine whether to conduct a full review or an expedited review. The Commission's determination in any expedited review will be based on the facts available, which may include information provided in response to this notice.

Definitions.—The following definitions apply to this review:

(1) *Subject Merchandise* is the class or kind of merchandise that is within the scope of the five-year review, as defined by the Department of Commerce.

(2) The *Subject Country* in this review is France.

(3) The *Domestic Like Product* is the domestically produced product or products which are like, or in the absence of like, most similar in characteristics and uses with, the *Subject Merchandise.* In its original determination and its full first and second five-year review determinations, the Commission defined one *Domestic Like Product* consisting of all low enriched uranium coextensive with Commerce's scope.

(4) The *Domestic Industry* is the U.S. producers as a whole of the *Domestic Like Product,* or those producers whose collective output of the *Domestic Like Product* constitutes a major proportion of the total domestic production of the product. In its original determination and its full first five-year review determination, the Commission determined that there was a single Domestic Industry consisting of the sole domestic producer of low enriched uranium at that time, USEC Inc. (''USEC''). The Commission also considered during its full first five-year review determination that the *Domestic Industry* would include Louisiana Energy Services (''LES'') within a reasonably foreseeable time. In its full second five-year review determination, the Commission defined the *Domestic Industry* to include LES and USEC, the two entities that produced the *Domestic Like Product* during the second five-year review.

(5) An *Importer* is any person or firm engaged, either directly or through a parent company or subsidiary, in importing the *Subject Merchandise* into the United States from a foreign manufacturer or through its selling agent.

Participation in the proceeding and public service list.—Persons, including industrial users of the *Subject Merchandise* and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the proceeding as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11(b)(4) of the Commission's rules, no later than 21 days after publication of this notice in the **Federal Register**. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the proceeding.

Former Commission employees who are seeking to appear in Commission five-year reviews are advised that they may appear in a review even if they participated personally and substantially in the corresponding underlying original investigation or an earlier review of the same underlying investigation. The Commission's designated agency ethics official has advised that a five-year review is not the same particular matter as the underlying original investigation, and a five-year review is not the same particular matter as an earlier review of the same underlying investigation for purposes of 18 U.S.C. 207, the post-employment statute for Federal employees, and Commission rule 201.15(b) (19 CFR 201.15(b)), 79 FR 3246 (Jan. 17, 2014), 73 FR 24609 (May 5, 2008). Consequently, former employees are not required to seek Commission approval to appear in a review under Commission rule 19 CFR 201.15, even if the corresponding underlying original investigation or an earlier review of the same underlying investigation was pending when they were Commission

employees. For further ethics advice on this matter, contact Charles Smith, Office of the General Counsel, at 202–205–3408.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and APO service list.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI submitted in this proceeding available to authorized applicants under the APO issued in the proceeding, provided that the application is made no later than 21 days after publication of this notice in the **Federal Register**. Authorized applicants must represent interested parties, as defined in 19 U.S.C. 1677(9), who are parties to the proceeding. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Certification.—Pursuant to section 207.3 of the Commission's rules, any person submitting information to the Commission in connection with this proceeding must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will acknowledge that information submitted in response to this request for information and throughout this proceeding or other proceeding may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

Written submissions.—Pursuant to section 207.61 of the Commission's rules, each interested party response to this notice must provide the information specified below. The deadline for filing such responses is December 3, 2018. Pursuant to section 207.62(b) of the Commission's rules, eligible parties (as specified in Commission rule 207.62(b)(1)) may also file comments concerning the adequacy of responses to the notice of institution and whether the Commission should conduct an expedited or full review. The deadline for filing such comments is January 14, 2019. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's Handbook on E-Filing, available on the Commission's website at *https://edis.usitc.gov,* elaborates upon the Commission's rules with respect to electronic filing. Also, in accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the proceeding must be served on all other parties to the proceeding (as identified by either the public or APO service list as appropriate), and a certificate of service must accompany the document (if you are not a party to the proceeding you do not need to serve your response).

No response to this request for information is required if a currently valid Office of Management and Budget (''OMB'') number is not displayed; the OMB number is 3117 0016/USITC No. 18–5–415, expiration date June 30, 2020. Public reporting burden for the request is estimated to average 15 hours per response. Please send comments regarding the accuracy of this burden estimate to the Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436.

Inability to provide requested information.—Pursuant to section 207.61(c) of the Commission's rules, any interested party that cannot furnish the information requested by this notice in the requested form and manner shall notify the Commission at the earliest possible time, provide a full explanation of why it cannot provide the requested information, and indicate alternative forms in which it can provide equivalent information. If an interested party does not provide this notification (or the Commission finds the explanation provided in the notification inadequate) and fails to provide a complete response to this notice, the Commission may take an adverse inference against the party pursuant to section 776(b) of the Act (19 U.S.C. 1677e(b)) in making its determination in the review.

Information to be provided in response to This Notice of Institution: As used below, the term ''firm'' includes any related firms.

(1) The name and address of your firm or entity (including World Wide Web address) and name, telephone number, fax number, and email address of the certifying official.

(2) A statement indicating whether your firm/entity is an interested party under 19 U.S.C. 1677(9) and if so, how, including whether your firm/entity is a U.S. producer of the *Domestic Like Product,* a U.S. union or worker group, a U.S. importer of the *Subject Merchandi*se, a foreign producer or exporter of the *Subject Merchandise,* a U.S. or foreign trade or business association (a majority of whose members are interested parties under the statute), or another interested party (including an explanation). If you are a union/worker group or trade/business association, identify the firms in which your workers are employed or which are members of your association.

(3) A statement indicating whether your firm/entity is willing to participate in this proceeding by providing information requested by the Commission.

(4) A statement of the likely effects of the revocation of the antidumping duty order on the *Domestic Industry* in general and/or your firm/entity specifically. In your response, please discuss the various factors specified in section 752(a) of the Act (19 U.S.C. 1675a(a)) including the likely volume of subject imports, likely price effects of subject imports, and likely impact of imports of *Subject Merchandise* on the *Domestic Industry.*

(5) A list of all known and currently operating U.S. producers of the *Domestic Like Product.* Identify any known related parties and the nature of the relationship as defined in section 771(4)(B) of the Act (19 U.S.C. 1677(4)(B)).

(6) A list of all known and currently operating U.S. importers of the *Subject Merchandise* and producers of the *Subject Merchandise* in the *Subject Country* that currently export or have exported *Subject Merchandise* to the United States or other countries after 2012.

(7) A list of 3–5 leading purchasers in the U.S. market for the *Domestic Like Product* and the *Subject Merchandise* (including street address, World Wide Web address, and the name, telephone number, fax number, and email address of a responsible official at each firm).

(8) A list of known sources of information on national or regional prices for the *Domestic Like Product* or the *Subject Merchandise* in the U.S. or other markets.

(9) If you are a U.S. producer of the *Domestic Like Product,* provide the following information on your firm's operations on that product during calendar year 2017, except as noted (report quantity data in separative work units (''SWUs'') and value data in U.S. dollars, f.o.b. plant). If you are a union/worker group or trade/business association, provide the information, on an aggregate basis, for the firms in which your workers are employed/which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total U.S. production of the *Domestic Like Product* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm to produce the *Domestic Like Product* (that is, the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix);

(c) the quantity and value of U.S. commercial shipments of the *Domestic Like Product* produced in your U.S. plant(s);

(d) the quantity and value of U.S. internal consumption/company transfers of the *Domestic Like Product* produced in your U.S. plant(s); and

(e) the value of (i) net sales, (ii) cost of goods sold (COGS), (iii) gross profit, (iv) selling, general and administrative (SG&A) expenses, and (v) operating income of the *Domestic Like Product* produced in your U.S. plant(s) (include both U.S. and export commercial sales, internal consumption, and company transfers) for your most recently completed fiscal year (identify the date on which your fiscal year ends).

(10) If you are a U.S. importer or a trade/business association of U.S. importers of the *Subject Merchandise* from the *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2017 (report quantity data in SWUs and value data in U.S. dollars). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) The quantity and value (landed, duty-paid but not including antidumping duties) of U.S. imports and, if known, an estimate of the percentage of total U.S. imports of *Subject Merchandise* from the *Subject Country* accounted for by your firm's(s') imports;

(b) the quantity and value (f.o.b. U.S. port, including antidumping duties) of U.S. commercial shipments of *Subject Merchandise* imported from the *Subject Country;* and

(c) the quantity and value (f.o.b. U.S. port, including antidumping duties) of U.S. internal consumption/company transfers of *Subject Merchandise* imported from the *Subject Country.*

(11) If you are a producer, an exporter, or a trade/business association of producers or exporters of the *Subject Merchandise* in the *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2017 (report quantity data in SWUs and value data in U.S. dollars, landed and duty-paid at the U.S. port but not including antidumping duties). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total production of *Subject Merchandise* in the *Subject Country* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm(s) to produce the *Subject Merchandise* in the *Subject Country* (that is, the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix); and

(c) the quantity and value of your firm's(s') exports to the United States of *Subject Merchandise* and, if known, an estimate of the percentage of total exports to the United States of *Subject Merchandise* from the *Subject Country* accounted for by your firm's(s') exports.

(12) Identify significant changes, if any, in the supply and demand conditions or business cycle for the *Domestic Like Product* that have occurred in the United States or in the market for the *Subject Merchandise* in the *Subject Country* after 2012, and significant changes, if any, that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the *Domestic Like Product* produced in the United States, *Subject Merchandise* produced in the *Subject Country,* and such merchandise from other countries.

(13) (OPTIONAL) A statement of whether you agree with the above definitions of the *Domestic Like Product* and *Domestic Industry;* if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

Authority: This proceeding is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.61 of the Commission's rules.

By order of the Commission.

Issued: October 26, 2018.

Katherine Hiner,

Supervisory Attorney.

[FR Doc. 2018–23850 Filed 10–31–18; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Air Act

On October 29, 2018, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Northern District of Illinois in the lawsuit entitled *United States* v. *Aux Sable Liquid Products L.P.,* Civil Action No. 1:18–cv–7198.

The United States filed the lawsuit under the Clean Air Act. The Consent Decree seeks to resolve claims for alleged violations at Aux Sable Liquid Products L.P.'s natural gas processing facility in Morris, Illinois, including (i) monitoring violations involving Leak Detection and Repair and (ii) excess emissions of volatile organic compounds in violation of Non-attainment New Source Review provisions of the Illinois State Implementation Plan. The proposed Consent Decree requires Aux Sable to pay a $2.7 million civil penalty and to perform certain compliance requirements and mitigation measures.

The publication of this notice opens a period for public comment on the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *Aux Sable Liquid Products L.P.,* D.J. Ref. No. 90–5–2–1–11203. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ–ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the proposed Consent Decree may be examined and downloaded at this Justice Department website: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ–ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $17.50 (25 cents per page reproduction cost) payable to the United States Treasury.

Randall Stone,

Acting Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2018–23915 Filed 10–31–18; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

U.S. Marshals Service

[OMB Number 1105–0097]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension With Change, of a Previously Approved Collection; Leased/Charter/Contract Personnel Expedited Clearance Request

AGENCY: U.S. Marshals Service, Department of Justice.

ACTION: 60-day notice.

SUMMARY: The Department of Justice (DOJ), U.S. Marshals Service (USMS), 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.

DATES: Comments are encouraged and will be accepted for 60 days until December 31, 2018.

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 additional information, please contact Nicole Timmons either by mail at CG–3, 10th Floor, Washington, DC 20530–0001, by email at *Nicole.Timmons@usdoj.gov,* or by telephone at 202–236–2646.

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 (*check justification or form 83): Extension of a currently approved collection.

2. *The Title of the Form/Collection:* Leased/Charter/Contract Personnel Expedited Clearance Request.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number (if applicable): USM–271.

Component: U.S. Marshals Service, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Individuals or households.

Abstract: This form is to be completed by people applying to become contract personnel. It is required so that USMS can perform an expedited background check before workers may be hired to transport USMS and Bureau of Prisons prisoners.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 180 respondents will utilize the form, and it will take each respondent approximately 5 minutes to complete the form.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated public burden associated with this collection is 15 hours. It is estimated that applicants will take 5 minutes to complete a Form USM–271. In order to calculate the public burden for Form USM–271, USMS multiplied 5 by 180 and divided by 60 (the number of minutes in an hour), which equals 15 total annual burden hours.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: October 29, 2018.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2018–23895 Filed 10–31–18; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Foreign Labor Certification Quarterly Activity Report

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL or Department) is submitting the Employment and Training Administration (ETA) sponsored information collection request (ICR) revision titled, ''Foreign Labor

Certification Quarterly Activity Report,'' to the Office of Management and Budget (OMB) for review and approval for use in accordance with the Paperwork Reduction Act (PRA) of 1995. Public comments on the ICR are invited.

DATES: OMB will consider all written comments that the agency receives on or before December 3, 2018.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the *RegInfo.gov* website at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201810-1205-002* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–ETA, Office of Management and Budget, Room 10235, 725 17th Street NW, Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor–OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW, Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: This ICR seeks approval under the PRA for revisions to the Foreign Labor Certification Quarterly Activity Report, information collection. Under the foreign labor certification programs administered by ETA, State Workforce Agencies (SWAs) are funded through annually reimbursable grants. These grants fund certain activities that support the processing of applications for temporary labor certification filed by U.S. employers in order to hire foreign workers in the H–2B or H–2A visa categories to perform nonagricultural or agricultural services or labor. Under the grant agreements, SWAs must review and transmit, through the intrastate and interstate systems, job orders submitted by employers in order to recruit U.S. workers prior to filling the job openings with foreign workers.

In order to monitor the administration of foreign labor certification activities by the SWAs effectively, the Department requires SWAs to report their workloads related to these activities on a quarterly basis. This collection of information is conducted through Form ETA–9127, *Foreign Labor Certification Quarterly Activity Report.* This report is critical for ensuring accountability and for future program management, including budget and workload management. This information collection has been classified as a revision, because of the proposed (1) elimination of a question referencing union contacts made by the SWAs; (2) elimination of a question located in both the H–2A and H–2B sections that prompts SWAs to list the most common deficiencies on the job order; and (3) modification of the Form ETA–9127 instructions in order to promote clarity as a result of some confusion expressed by SWAs. Immigration and Nationality Act section 218 authorizes this information collection. *See* 8 U.S.C. 1188.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. DOL obtains OMB approval for this information collection under Control Number 1205–0457. The DOL notes that existing information collection requirements submitted to OMB receive a month-to-month extension while they undergo review. New requirements would only take effect upon OMB approval. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on June 21, 2018 (83 FR 28866).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1205–0457. OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: DOL–ETA.

Title of Collection: Foreign Labor Certification Quarterly Activity Report.

OMB Control Number: 1205–0457.

Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Respondents: 54.

Total Estimated Number of Responses: 216.

Average Time per Response: 1 hour 45 minutes.

Total Estimated Annual Time Burden: 378 hours.

Total Estimated Annual Other Costs Burden: $0.

Authority: 44 U.S.C. 3507(a)(1)(D).

Dated: October 26, 2018.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2018–23866 Filed 10–31–18; 8:45 am]

BILLING CODE 4510–FP–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request, Evaluation of the American Apprenticeship Initiative, New Collection

AGENCY: Office of the Assistant Secretary for Policy, Chief Evaluation Office, Department of Labor.

ACTION: Notice of Information Collection; request for comment.

SUMMARY: The Department of Labor (DOL), as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of

information in accordance with the Paperwork Reduction Act of 1995 (PRA95). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents is properly assessed. Currently, the Department of Labor is soliciting comments concerning the collection of data about the Evaluation of Strategies Used in America's Promise Job Driven Grant Program Evaluation. A copy of the proposed Information Collection Request (ICR) can be obtained by contacting the office listed below in the addressee section of this notice.

DATES: Written comments must be submitted to the office listed in the addressee section below on or before December 31, 2018.

ADDRESSES: You may submit comments by either one of the following methods:

Email: ChiefEvaluationOffice@dol.gov; Mail or Courier: Megan Lizik, Chief Evaluation Office, OASP, U.S. Department of Labor, Room S–2312, 200 Constitution Avenue NW, Washington, DC 20210. *Instructions:* Please submit one copy of your comments by only one method. All submissions received must include the agency name and OMB Control Number identified above for this information collection. Comments, including any personal information provided, become a matter of public record. They will also be summarized and/or included in the request for OMB approval of the information collection request.

FOR FURTHER INFORMATION CONTACT: Megan Lizik by email at *ChiefEvaluationOffice@dol.gov,* or call 202–430–1255.

SUPPLEMENTARY INFORMATION:

I. *Background:* The Chief Evaluation Office (CEO) of the U.S. Department of Labor (DOL) intends to design and conduct an evaluation to assess the success of the America's Promise Job Driven Grant Program (America's Promise). The goal of this project is to build knowledge about the effectiveness and implementation of the program. The evaluation of America's Promise includes two components: (1) An impact evaluation to measure the effects of America's Promise on participant outcomes and (2) an implementation evaluation to understand program implementation and partnership development for all 23 grantees. The implementation evaluation includes more detailed focus on program implementation in 12 grantees and a measurement of partnerships and systems change in six grantees. This request is part of a larger study which has had other components, a grantee survey and partner network survey, submitted for approval in an earlier clearance request. A 60-day notice to solicit public comments on that package was published in the **Federal Register**, 82 FR 32204 on July 12, 2017.

This **Federal Register** Notice provides the opportunity to comment on proposed data collection instruments that will be used in the implementation evaluation: Semi-structured program stakeholder interview protocols, participant focus group protocols, and semi-structured telephone interview protocols

1. *Semi-structured program stakeholder interview protocols.* Site visits to approximately 12 grantees will occur in fall 2019. These visits will last two and a half days each. During these site visits, we will conduct one-on-one or small-group semi-structured interviews with a broad range of stakeholders, including grantee staff, partner staff, employers, training and education providers, and community stakeholders. We will also observe program activities to help us describe key program components, assess the quality of program delivery, and understand participant needs. The observations will not involve additional burden.

2. Participant focus group protocols. Also during the site visits, we will conduct one focus group per site with approximately five program participants.

3. *Semi-structured telephone interview protocols.* For approximately 11 sites that do not receive in-person visits, we will conduct about two-hour in-depth telephone interviews with grantee managers and partners to cover a subset of the information collected in the site visits. The information requested from these phone calls may be tailored to the circumstances of each grantee.

II. *Desired Focus of Comments:* Currently, the Department of Labor is soliciting comments concerning the above data collection for the Evaluation of Strategies Used in the America's Promise Job Driven Grant Program Evaluation. DOL is particularly interested in comments that do the following:

○ Evaluate whether the proposed collection of information is necessary for the proper performance functions of the agency, including whether the information will have practical utility;

○ evaluate the accuracy of the agency's burden estimate of the proposed information collection, including the validity of the methodology and assumptions;

○ enhance the quality, utility, and clarity of the information to be collected; and

○ minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology—for example, permitting electronic submissions of responses.

III. *Current Actions:* At this time, the Department of Labor is requesting clearance for the semi-structured program stakeholder interview protocols, participant focus group protocols, and semi-structured telephone interview protocols.

Type of Review: New information collection request.

OMB Control Number: 1290–0NEW.

Affected Public: America's Promise Job Driven Grant Program Evaluation grantees, partners and participants.

Comments submitted in response to this request will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

ESTIMATED ANNUAL BURDEN HOURS

Type of instrument (form/activity)	Number of respondents	Number of responses per respondent	Total number of responses	Average burden time per response (hours)	Estimated burden hours
Semi-structured program stakeholder interview protocol	[1] 40	1	40	1.5	60
Participant focus group protocol	[2] 20	1	20	1.5	30

ESTIMATED ANNUAL BURDEN HOURS—Continued

Type of instrument (form/activity)	Number of respondents	Number of responses per respondent	Total number of responses	Average burden time per response (hours)	Estimated burden hours
Semi-structured telephone interview protocol	[3] 15	1	15	2	30
Total	75		75		120

[1] Assumes approximately 10 semi-structured interview participants during each site visit at approximately 12 grantees: 5 program staff members and 5 program partners over the three-year clearance period.
[2] Assumes approximately 5 program participants at each focus group for approximately 12 grantees over the three-year clearance period.
[3] Assumes approximately 4 telephone participants per approximately 11 grantees: 2 program staff members and 2 program partners over the three-year clearance period.

Molly Irwin,

Chief Evaluation Officer, U.S. Department of Labor.

[FR Doc. 2018–23703 Filed 10–31–18; 8:45 am]

BILLING CODE 4510–HX–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–2019–005]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice.

SUMMARY: NARA gives public notice that it proposes to request extension of two currently approved information collections. The first information collection is used when former Federal civilian employees and other authorized individuals request information from or copies of documents in Official Personnel Folders or Employee Medical Folders from the National Personnel Records Center (NPRC) of the National Archives and Records Administration (NARA). The second information collection is NA Form 6045, Volunteer Service Application, used by individuals who wish to volunteer at the National Archives Building, the National Archives at College Park, regional records services facilities, and Presidential Libraries. We invite you to comment on these proposed information collections pursuant to the Paperwork Reduction Act of 1995.

DATES: We must receive written comments on or before December 31, 2018.

ADDRESSES: Send comments to Paperwork Reduction Act Comments (MP), Room 4100; National Archives and Records Administration; 8601 Adelphi Road; College Park, MD 20740–6001, fax them to 301–837–0319, or email them to *tamee.fechhelm@nara.gov.*

FOR FURTHER INFORMATION CONTACT: Contact Tamee Fechhelm by telephone at 301–837–1694 or fax at 301–837–0319 with requests for additional information or copies of the proposed information collections and supporting statements.

SUPPLEMENTARY INFORMATION: Pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13), NARA invites the public and other Federal agencies to comment on proposed information collections. The comments and suggestions should address one or more of the following points: (a) Whether the proposed information collection is necessary for NARA to properly perform its functions; (b) NARA's estimate of the burden of the proposed information collection and its accuracy; (c) ways NARA could enhance the quality, utility, and clarity of the information it collects; (d) ways NARA could minimize the burden on respondents of collecting the information, including through information technology; and (e) whether the collection affects small businesses. We will summarize any comments you submit and include the summary in our request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this notice, NARA solicits comments concerning the following information collections:

1. *Title:* Forms relating to civilian service records.

OMB number: 3095–0037.

Agency form number: NA Forms 13022, 13064, 13068.

Type of review: Regular.

Affected public: Former Federal civilian employees, their authorized representatives, state and local governments, and businesses.

Estimated number of respondents: 32,060.

Estimated time per response: 5 minutes.

Frequency of response: On occasion, when individuals desire to acquire information from Federal civilian employee personnel or medical records.

Estimated total annual burden hours: 2,671 hours.

Abstract: In accordance with rules issued by the Office of Personnel Management, the National Personnel Records Center (NPRC) of the National Archives and Records Administration (NARA) administers Official Personnel Folders (OPF) and Employee Medical Folders (EMF) of former Federal civilian employees. When former Federal civilian employees and other authorized individuals request information from or copies of documents in OPF or EMF, they must provide in forms or in letters certain information about the employee and the nature of the request. The NA Form 13022, Returned Request Form, is used to request additional information about the former Federal employee. The NA Form 13064, Reply to Request Involving Relief Agencies, is used to request additional information about the former relief agency employee. The NA Form 13068, Walk-In Request for OPM Records or Information, is used by members of the public, with proper authorization, to request a copy of a Personnel or Medical record.

2. *Title:* Volunteer service application.

OMB number: 3095–0060.

Agency form number: NA Forms 6045, 6045a, 6045b, and 6045c.

Type of review: Regular.

Affected public: Individuals or households.

Estimated number of respondents: 500.

Estimated time per response: 25 minutes.

Frequency of response: On occasion.

Estimated total annual burden hours: 208 hours.

Abstract: NARA uses volunteer resources to enhance its services to the public and to further its mission of providing ready access to essential evidence. Volunteers assist in outreach and public programs and provide

technical and research support for administrative, archival, library, and curatorial staff. NARA uses a standard way to recruit volunteers and assess the qualifications of potential volunteers. The NA Form 6045, Volunteer Service Application, is used by members of the public to signal their interest in being a NARA volunteer and to identify their qualifications for this work. Once the applicant has been selected, the NA Form 6045a, Standards of Conduct for Volunteers, NA Form 6045b, Volunteer or Intern Emergency and Medical Consent, NA Form 6045c, Volunteer or Intern Confidentiality Statement, are filled out.

Swarnali Haldar,

Executive for Information Services/CIO.

[FR Doc. 2018–23873 Filed 10–31–18; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–2019–004]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice.

SUMMARY: NARA is giving public notice that it has submitted to OMB for approval the information collection described in this notice. We invite you to comment on the proposed information collection pursuant to the Paperwork Reduction Act of 1995.

DATES: OMB must receive written comments at the address below on or before December 3, 2018.

ADDRESSES: Send comments to Mr. Nicholas A. Fraser, desk officer for NARA, by mail to Office of Management and Budget; New Executive Office Building; Washington, DC 20503; fax to 202–395–5167; or by email to *Nicholas_A._Fraser@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information or copies of the proposed information collection and supporting statement to Tamee Fechhelm by phone at 301–837–1694 or by fax at 301–837–0319.

SUPPLEMENTARY INFORMATION: Pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13), NARA invites the general public and other Federal agencies to comment on proposed information collections. We published a notice of proposed collection for this information collection on August 16, 2018 (83 FR 40789); and we received no comments. We have therefore submitted the described information collection to OMB for approval.

In response to this notice, comments and suggestions should address one or more of the following points: (a) Whether the proposed information collection is necessary for NARA to properly perform its functions; (b) NARA's estimate of the burden of the proposed information collection and its accuracy; (c) ways NARA could enhance the quality, utility, and clarity of the information it collects; (d) ways NARA could minimize the burden on respondents of collecting the information, including through information technology; and (e) whether the collection affects small businesses. In this notice, NARA solicits comments concerning the following information collection:

Title: Independent researcher listing application.

OMB number: 3095–0054.

Agency form numbers: NA Form 14115.

Type of review: Regular.

Affected public: Individuals or households.

Estimated number of respondents: 458.

Estimated time per response: 10 minutes.

Frequency of response: On occasion.

Estimated total annual burden hours: 76.

Abstract: In the past, the National Archives has made use of various lists of independent researchers who perform freelance research for hire in the Washington, DC, area. We have sent these lists upon request to researchers who could not travel to the metropolitan area to conduct their own research. To better accommodate both the public and NARA staff, the Customer Services Division (RD–DC) of the National Archives maintains a listing of independent researchers for the public. All interested independent researchers provide their contact information via this form. Collecting contact and other key information from each independent researcher and providing such information to the public when deemed appropriate will only increase business. This form is not a burden in any way to any independent researcher who voluntarily submits a completed form. Inclusion on the list will not be viewed or advertised as an endorsement by the National Archives and Records Administration (NARA). The listing is compiled and disseminated as a service to the public.

Swarnali Haldar,

Executive for Information Services/CIO.

[FR Doc. 2018–23872 Filed 10–31–18; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–2019–003]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice.

SUMMARY: NARA is giving public notice that it has submitted to OMB for approval the information collections described in this notice. We invite you to comment on the proposed information collections pursuant to the Paperwork Reduction Act of 1995.

DATES: OMB must receive written comments at the address below on or before December 3, 2018.

ADDRESSES: Send comments to Mr. Nicholas A. Fraser, desk officer for NARA, by mail to Office of Management and Budget; New Executive Office Building; Washington, DC 20503; fax to 202–395–5167; or by email to *Nicholas_A._Fraser@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information or copies of the proposed information collection and supporting statement to Tamee Fechhelm by phone at 301–837–1694 or by fax at 301–837–0319.

SUPPLEMENTARY INFORMATION: Pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13), NARA invites the general public and other Federal agencies to comment on proposed information collections. We published a notice of proposed collection for this information collection on July 27, 2018 (83 FR 35681); and we received no comments. We have therefore submitted the described information collection to OMB for approval.

In response to this notice, comments and suggestions should address one or more of the following points: (a) Whether the proposed information collection is necessary for NARA to properly perform its functions; (b) NARA's estimate of the burden of the proposed information collection and its accuracy; (c) ways NARA could enhance the quality, utility, and clarity of the information it collects; (d) ways NARA

could minimize the burden on respondents of collecting the information, including through information technology; and (e) whether the collection affects small businesses. In this notice, NARA solicits comments concerning the following information collections:

1. *Title:* Request to digitize records.
OMB number: 3095–0017.
Agency form number: None.
Type of review: Regular.
Affected public: Companies and organizations that wish to digitize archival holdings in the National Archives of the United States or a Presidential library for micropublication.
Estimated number of respondents: 10.
Estimated time per response: 5 hours.
Frequency of response: On occasion (when respondent wishes to request permission to digitize records).
Estimated total annual burden hours: 50.
*Abstrac*t: The information collection is prescribed by 36 CFR 1254.92. The collection is prepared by companies and organizations that wish to digitize archival holdings with privately-owned equipment. NARA uses the information to determine whether the request meets the criteria in 36 CFR 1254.94, to evaluate the records for digitization, and to schedule use of the limited space available for digitizing.

2. *Title:* Request to film, photograph, or videotape at a NARA facility for news purposes.
OMB number: 3095–0040.
Agency form number: None.
Type of review: Regular.
*Affected publi*c: Business or other for-profit, not-for-profit institutions.
Estimated number of respondents: 350.
Estimated time per response: 10 minutes.
Frequency of response: On occasion.
Estimated total annual burden hours: 58.
Abstract: The information collection is prescribed by 36 CFR 1280.48. The collection is prepared by organizations that wish to film, photograph, or videotape on NARA property for news purposes. NARA needs the information to determine if the request complies with NARA's regulations, to ensure protection of archival holdings, and to schedule the filming appointment.

3. *Title:* Request to use NARA facilities in the Washington, DC area for events.
OMB number: 3095–0043.
Agency form number: None.
Type of review: Regular.
Affected public: Not-for-profit institutions, individuals or households, business or other for-profit, Federal Government.
Estimated number of respondents: 530.
Estimated time per response: Between 5 and 30 minutes.
Frequency of response: On occasion.
Estimated total annual burden hours: 169.
Abstract: The information collection is prescribed by 36 CFR 1280.80 and 1280.82. The collection is prepared by organizations that wish to use NARA public areas in the Washington, DC area for an event. NARA uses the information to determine whether or not we can accommodate the request and to ensure that the proposed event complies with NARA regulations.

Swarnali Haldar,
Executive for Information Services/CIO.
[FR Doc. 2018–23871 Filed 10–31–18; 8:45 am]
BILLING CODE 7515–01–P

NATIONAL SCIENCE FOUNDATION

National Science Board; Sunshine Act Meetings

The National Science Board's Committee on External Engagement (EE), pursuant to NSF regulations (45 CFR part 614), the National Science Foundation Act, as amended (42 U.S.C. 1862n–5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice of the scheduling of a teleconference for the transaction of National Science Board business, as follows:

TIME AND DATE: Monday, November 5, 2018, from 5:00–6:00 p.m. EST.

PLACE: This meeting will be held by teleconference at the National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314. An audio link will be available for the public. Members of the public must contact the Board Office to request the public audio link by sending an email to *nationalsciencebrd@nsf.gov* at least 24 hours prior to the teleconference.

STATUS: Open.

MATTERS TO BE CONSIDERED: Chair's opening remarks; prepare for the November Board meeting by discussing key initiatives of the committee, including a NSB alumni initiative, meetings with Members of Congress during the Home District work periods, and additional NSB one-pagers on key science policy issues.

CONTACT PERSON FOR MORE INFORMATION: Point of contact for this meeting is: Nadine Lymn (*nlymn@nsf.gov*), 2415 Eisenhower Avenue, Alexandria, VA 22314.

Meeting information and updates may be found at *http://www.nsf.gov/nsb/notices/.jsp#sunshine.* Please refer to the National Science Board website at *www.nsf.gov/nsb* for general information.

Chris Blair,
Executive Assistant to the National Science Board Office.
[FR Doc. 2018–23948 Filed 10–30–18; 11:15 am]
BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Proposal Review Panel for Computing and Communication Foundations; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub., L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting:

Name and Committee Code: Proposal Review Panel for Computing and Communication Foundations (#1192)—CSoI (Purdue University) Reverse Site Visit.
Date and Time: December 4, 2018; 8:00 a.m.—5:00 p.m.
Place: Virginia Tech Research Center, 900 Glebe Road, Arlington, VA 22203.
Type of Meeting: Part-Open.
Contact Person: Phillip Regalia, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA, 22314; Telephone: (703) 292–8910.
Purpose of Meeting: Reverse site visit to assess the progress of the STC Award: CCF-0939370, ''Emerging Frontiers of Science of Information'', and to provide advice and recommendations concerning further support for the project.

Agenda

Tuesday, December 4, 2018; 8:00 a.m.–3:00 p.m.

8:00 a.m. to 3:00 p.m.: OPEN

Presentations by Awardee Institution, faculty staff and students, to Site Team and NSF Staff. Discussions, question and answer sessions.

3:00 p.m.–5:00 p.m.: CLOSED

Response and feedback to presentations by Site Team and NSF Staff. Discussions, question and answer sessions. Draft report on education and research activities. Complete written site visit report with preliminary recommendations.

Reason for Closing: The work being reviewed during closed portions of the reverse site review include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the review.

These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: October 29, 2018.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2018–23882 Filed 10–31–18; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Biological Sciences; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting:

Name and Committee Code: Advisory Committee for Biological Sciences (#1110).

Date and Time: November 15, 2018; 1 p.m.–3 p.m.

Place: National Science Foundation, 2415 Eisenhower Avenue, Room E 3410, Alexandria, VA 22314.

Please contact Alexis Patullo at *apatullo@nsf.gov* to obtain a visitor badge. All visitors to the NSF will be required to show photo ID to obtain a badge.

Type of Meeting: Open.

Contact Person: Nancy Sung, National Science Foundation, 2415 Eisenhower Avenue, Room C 12031, Alexandria, VA 22314; Tel No.: (703) 292–8400.

Purpose of Meeting: The Advisory Committee for the Directorate for Biological Sciences (BIO) provides advice, recommendations, and oversight concerning major program emphases, directions, and goals for the research-related activities of the divisions that make up BIO.

Agenda: This meeting will be held telephonically among the Advisory Committee members; public visitors will be able to attend the meeting in person at NSF headquarters. Agenda items will include discussion of establishment of a BIO AC subcommittee on proposal submission limits.

Dated: October 29, 2018.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2018–23858 Filed 10–31–18; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–280 and 50–281; NRC–2018–0247]

Virginia Electric and Power Company; Dominion Energy Virginia; Surry Power Station, Units 1 and 2

AGENCY: Nuclear Regulatory Commission.

ACTION: License renewal application; receipt.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has received an application for the subsequent renewal of Renewed Facility Operating License Nos. DPR–32 and DPR–37, which authorize Virginia Electric and Power Company (Dominion Energy Virginia or the applicant) to operate Surry Power Station (SPS), Units 1 and 2. The renewed licenses would authorize the applicant to operate SPS for an additional 20 years beyond the period specified in each of the current renewed licenses. The current renewed operating licenses for SPS expire as follows: Unit 1 on May 25, 2032, and Unit 2 on January 29, 2033.

DATES: The license renewal application referenced in this document was available on October 24, 2018.

ADDRESSES: Please refer to Docket ID NRC–2018–0247 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2018–0247. Address questions about *Regulations.gov* Docket IDs to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Emmanuel Sayoc, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001; telephone: 301–415–4084, email: *Emmanuel.Sayoc@nrc.gov.*

SUPPLEMENTARY INFORMATION: The NRC has received an application (ADAMS Package Accession No. ML18291A842) from Virginia Electric and Power Company (Dominion Energy Virginia or the applicant), dated October 16, 2018, filed pursuant to Section 103 of the Atomic Energy Act of 1954, as amended, and part 54 of title 10 of the *Code of Federal Regulations*, to renew the operating licenses for SPS. Renewal of the licenses would authorize the applicant to operate the facility for an additional 20-year period beyond the period specified in the respective current renewed operating licenses. The current renewed operating licenses for SPS expire as follows: Unit 1 on May 25, 2032, and Unit 2 on January 29, 2033. The SPS units are Pressurized Water Reactors located in Surry, Virginia. The acceptability of the tendered application for docketing, and other matters, including an opportunity to request a hearing, will be the subject of subsequent **Federal Register** notices.

A copy of the license renewal application for SPS, is also available for inspection near the site, at the Williamsburg Library, 515 Scotland St., Williamsburg, VA 23185.

Dated at Rockville, Maryland, this 26th day of October 2018.

For the Nuclear Regulatory Commission.

David M. Drucker,

Acting Chief, License Renewal Project Branch, Division of Materials and License Renewal, Office of Nuclear Reactor Regulation.

[FR Doc. 2018–23841 Filed 10–31–18; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 52–025 and 52–026; NRC–2008–0252]

Southern Nuclear Operating Company, Inc., Vogtle Electric Generating Plant, Units 3 and 4; Exemptions

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing an exemption in response to a June 27, 2018, request from Southern Nuclear Operating Company, Inc., as applicable to Vogtle Electric Generating Plant (VEGP) Units 3 and 4. Specifically, SNC requested an exemption that would modify the requirement for the level 1 and level 2 PRA for VEGP Units 3 and 4 to cover those initiating events and modes for which Regulatory Guide 1.200, Revision 2, endorses standards.

DATES: The exemption was issued on October 26, 2018.

ADDRESSES: Please refer to Docket ID NRC–2008–0252 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

• *Federal Rulemaking Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2008–0252. Address questions about *Regulations.gov* Docket IDs to Jennifer Borges, telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*Begin Web-based ADAMS Search*.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document. The request for the amendment and exemption was submitted by letter dated April 20, 2018, and available in ADAMS under Accession No. ML18110A113.

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Chandu Patel, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–3025; email: *Chandu.Patel@nrc.gov.*

I. Background

Southern Nuclear Operating Company, Inc., and Georgia Power Company, Oglethorpe Power Corporation, MEAG Power SPVM, LLC, MEAG Power SPVJ, LLC, MEAG Power SPVP, LLC, and the City of Dalton, Georgia (collectively SNC) are the holder of facility Combined License (COL) Nos. NFP–91 and NPF–92, which authorize the construction and operation of Vogtle Electric Generating Plant (VEGP) Units 3 and 4. The COLs, issued under part 52 of title 10 of the *Code of Federal Regulations* (10 CFR), provide, among other things, that the facilities are subject to all rules, regulations, and orders of the NRC or the Commission now or hereafter in effect. The facilities consist of two AP1000 pressurized-water reactors located in Burke County, Georgia.

Section 10 CFR 50.71(h)(1) requires each holder of a COL, no later than the scheduled date for initial loading of fuel, to develop a level 1 and a level 2 probabilistic risk assessment (PRA) that covers those initiating events and modes for which NRC-endorsed consensus standards on PRA exist one year prior to the scheduled date for initial loading of fuel. Based on the anticipated timing of the VEGP Unit 3 fuel load, the PRA development for VEGP Units 3 and 4 is proceeding in accordance with the current PRA consensus standards in Regulatory Guide (RG) 1.200, ''An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities,'' Revision 2. However, the next revision to RG 1.200 may take place more than one year prior to fuel load at VEGP Unit 3 and/or VEGP Unit 4; therefore, it is possible that the PRA for VEGP Unit 3 and/or VEGP Unit 4 could be required to cover new initiating events and modes. Based on a review of the scope of work for SNC's PRA development, a requirement that SNC meet new PRA standards established one year or more prior to the scheduled fuel load date could delay fuel load until the PRA was completed. It is, therefore, not practicable for SNC to shift PRA development from Rev. 2 of RG 1.200 to newly endorsed standards as required by 10 CFR 50.71(h)(1).

II. Request/Action

Pursuant to 10 CFR 50.12, ''Specific exemptions,'' SNC requested, by letter dated June 27, 2018 (ADAMS Accession No. ML18178A533), an exemption from the requirements of 10 CFR 50.71(h)(1), as applicable to VEGP Units 3 and 4. Specifically, SNC requested an exemption that would modify the requirement for the level 1 and level 2 PRA for VEGP Units 3 and 4 to cover those initiating events and modes for which RG 1.200, Rev. 2, endorses standards. Thus, under the requested exemption, SNC would be required to meet the PRA standards in RG 1.200, Rev. 2, for initial fuel loading at VEGP Units 3 and 4, even if the NRC endorses new standards on PRA one year or more prior to the scheduled fuel load date at VEGP Unit 3 or Unit 4. The requested exemption from 10 CFR 50.71(h)(1) applies to the development of the VEGP Units 3 and 4 level 1 and level 2 PRA, but SNC still must follow the PRA upgrade requirements in 10 CFR 50.71(h)(2). Therefore, the effect of the requested exemption would be temporary, as the upgraded PRA must cover initiating events and modes of operation contained in NRC-endorsed consensus standards on PRA in effect one year prior to each required upgrade under 10 CFR 50.71(h)(2).

III. Discussion

Pursuant to 10 CFR 50.12, the Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR part 50 when (1) the exemptions are authorized by law, will not present an undue risk to public health and safety, and are consistent with the common defense and security; and (2) when special circumstances are present. These special circumstances include, among other things, when application of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule.

• *The Exemption Is Authorized by Law*

This exemption would allow SNC to modify the requirement for the level 1 and level 2 PRA developed prior to initial fuel loading for VEGP Units 3 and 4 to cover those initiating events and modes for which RG 1.200, Rev. 2, endorses standards. As stated above, 10 CFR 50.12 allows the NRC to grant exemptions from the requirements of 10 CFR part 50. The NRC staff has determined that granting of SNC's proposed exemption will not result in a violation of the Atomic Energy Act of 1954, as amended, or the Commission's regulations. Therefore, the exemption is authorized by law.

• *The Exemption Presents No Undue Risk to Public Health and Safety*

The proposed exemption from the requirements of 10 CFR 50.71(h)(1) would allow SNC to develop the level 1 and level 2 PRA to cover those initiating events and modes for which RG 1.200, Rev. 2, endorses standards. The change is needed to allow SNC sufficient time to fulfill the requirement.

Making the changes proposed in the exemption request would not adversely affect SNC's ability to satisfy other PRA requirements in the regulations or COLs. Using the standards currently endorsed by RG 1.200, Rev. 2, instead of potential newly endorsed standards, will continue to provide adequate protection of public health and safety. Risk insights from the design certification have already been incorporated into the design. Additionally, the proposed exemption does not introduce any new industrial, chemical, or radiological hazards that would present a public

health or safety risk, nor does it modify or remove any design or operational controls or safeguards intended to mitigate any existing on-site hazards. The proposed exemption does not allow for a new fission product release path, result in a new fission product barrier failure mode, or create a new sequence of events that would result in fuel cladding failures. Accordingly, the exemption does not present an undue risk to the public health and safety.

• *The Exemption Is Consistent With the Common Defense and Security*

The exemption would allow SNC to develop the level 1 and level 2 PRA prior to initial fuel loading for VEGP Units 3 and 4 to cover those initiating events and modes for which RG 1.200, Rev. 2, endorses standards. The change does not alter or impede the design, function, or operation of any plant structures, systems, or components associated with the facility's physical or cyber security and, therefore, does not affect any plant equipment that is necessary to maintain a safe and secure plant status. In addition, the changes have no impact on plant security or safeguards. Therefore, the staff has determined that this exemption does not adversely impact common defense and security.

• *Special Circumstances*

Special circumstances, in accordance with 10 CFR 50.12(a)(2)(ii), are present whenever application of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule. The underlying purpose of 10 CFR 50.71(h) is to require COL holders to maintain and upgrade a PRA to meet endorsed standards over the lifetime of the facility. Under the proposed exemption SNC would be required to use the endorsed standards in RG 1.200, Rev. 2, which would provide sufficient time for SNC to develop the level 1 and level 2 PRA required by 10 CFR 50.71(h)(1). Subsequently, 10 CFR 50.71(h)(2) and 10 CFR 50.71(h)(3) will continue to require SNC to maintain and upgrade the VEGP Units 3 and 4 PRA to meet future endorsed standards over the lifetime of the facilities.

Moreover, the underlying purpose of 10 CFR 50.71(h)(1) is to ensure that before beginning to operate, SNC has developed a PRA that accurately models the plant as it has been built and as it will be operated. The requested exemption from 10 CFR 50.71(h)(1) serves only to remove a degree of uncertainty as to which consensus standards will apply to the PRA model for VEGP Units 3 and 4. A plant-specific PRA that meets the standards endorsed by RG 1.200, Rev. 2, has been and will remain adequate until it is upgraded in accordance with 10 CFR 50.71(h)(2). Therefore, the underlying purposes of 10 CFR 50.71(h)(1) would be achieved by requiring the level 1 and level 2 PRA to meet currently endorsed standards. For the reasons discussed above, applying the provisions of 10 CFR 50.71(h)(1) addressed by the exemption request is not necessary to meet the underlying purpose of the rule. Therefore, the special circumstances required by 10 CFR 50.12(a)(2)(ii) for the granting of an exemption from 10 CFR 50.71(h)(1) exist.

Additionally, special circumstances, in accordance with 10 CFR 50.12(a)(2)(iii), are present whenever compliance would result in undue hardship or other costs that are significantly in excess of those contemplated when the regulation was adopted, or that are significantly in excess of those incurred by others similarly situated. The time required to update the PRA model to the new standards (which may include new initiating events and modes), peer review the model, resolve facts and observations from the peer review, and perform the plant walkdown is likely to take longer than one year, which could delay fuel load until the PRA was completed. In that case, compliance with 10 CFR 50.71(h)(1) would result in undue hardship or other costs that are significantly in excess of those contemplated when the regulation was adopted with no significant benefit to safety; therefore, the special circumstances required by 10 CFR 50.12(a)(2)(iii) for the granting of an exemption from 10 CFR 50.71(h)(1) exist.

• *Environmental Considerations*

The NRC staff determined that the exemption discussed herein meets the eligibility criteria for the categorical exclusion set forth in 10 CFR 51.22(c)(25) because the request seeks to change the timing of standards required by 10 CFR 50.71(h)(1) but does not make changes to the facility or operating procedures. Under 10 CFR 51.22(c)(25), granting of an exemption from the requirements of any regulation of chapter I to 10 CFR is a categorical exclusion provided that (i) there is no significant hazards consideration; (ii) there is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite; (iii) there is no significant increase in individual or cumulative public or occupational radiation exposure; (iv) there is no significant construction impact; (v) there is no significant increase in the potential for or consequences from radiological accidents; and (vi) the requirements from which an exemption is sought involve certain categories of requirements, such as reporting requirements related to the timing of using NRC-endorsed consensus standards on PRA, which detail the initiating events and modes that must be covered in the PRA.

As required by 10 CFR 51.22(c)(25)(i), and using the criteria set out in 10 CFR 50.92(c), the NRC staff reviewed whether the exemption request involves no significant hazards consideration.

(1) Does the requested exemption involve a significant increase in the probability or consequences of an accident previously evaluated?

No. The proposed exemption from the requirements of 10 CFR 50.71(h)(1) would allow SNC to develop the level 1 and level 2 PRA to cover those initiating events and modes for which RG 1.200, Rev. 2, endorses standards. The requested exemption does not alter the design, function, or operation of any plant equipment. Therefore, granting this exemption would not involve a significant increase in the probability or consequences of an accident previously evaluated.

(2) Does the requested exemption create the possibility of a new or different kind of accident from any accident previously evaluated?

No. The requested exemption does not alter the design, function, or operation of any plant equipment. The requested exemption does not create any new failure mechanisms, malfunctions, or accident initiators. Therefore, granting this exemption does not create the possibility of a new or different kind of accident from any accident previously evaluated.

(3) Does the requested exemption involve a significant reduction in a margin of safety?

No. A PRA is an analysis to determine the relative risk (probability) of an undesirable outcome, specifically, core damage frequency and large early release frequency.

While the PRA uses the design attributes of structures, systems, and components (SSCs), the PRA does not affect SSCs. As a result, a change to the PRA description or PRA results does not affect an SSC, SSC design function, or method of performing or controlling a design function. While the PRA uses the design attributes of SSCs, the PRA is not used to establish the design bases of an SSC nor is it used in the safety analyses. Furthermore, the requested exemption

does not exceed or alter a design basis or safety limit. Therefore, granting this exemption does not involve a significant reduction in a margin of safety.

As all of the responses to the above questions are in the negative, under 10 CFR 51.22(c)(25)(i), the NRC staff has concluded that the requested exemption involves no significant hazards consideration.

The requested exemption does not alter the design, function, or operation of any plant equipment. There are no changes to effluent types, plant radiological or non-radiological effluent release quantities, any effluent release path, or the functionality of any design or operational features credited with controlling the release of effluents during plant operation or construction. Therefore, under 10 CFR 51.22(c)(25)(ii), the NRC staff concludes that the proposed exemption does not involve a significant change in the types or significant increase in the amounts of any effluents that may be released offsite.

There are no changes to plant radiation zones and no changes to controls required under 10 CFR part 20, which preclude a significant increase in occupational radiation exposure. Therefore, under 10 CFR 51.22(c)(iii), the NRC staff concludes that the proposed exemption does not involve a significant increase in individual or cumulative public or occupational radiation exposure.

The requested exemption does not alter the design, function, or operation of any plant equipment. No change to the facility is being made as a result of this exemption. Therefore, under 10 CFR 51.22(c)(iv), the NRC staff concludes that the proposed exemption does not involve a significant construction impact.

The requested exemption does not alter the design, function, or operation of any plant equipment. There are no changes to plant radiation zones and no changes to controls required under 10 CFR part 20, which preclude a significant increase in occupational radiation exposure.

Therefore, under 10 CFR 51.22(c)(v), the NRC staff concludes that the proposed exemption does not involve a significant increase in the potential for or consequences from radiological accidents.

The requested exemption involves reporting requirements related to the timing of using NRC-endorsed consensus standards on PRA which detail the initiating events and modes that must be covered in the PRA. Therefore, under 10 CFR 51.22(c)(vi)(B), the NRC staff concludes that the proposed exemption involves a reporting requirement.

Based on the evaluation above, the NRC staff concludes that the exemption meets the criteria of 10 CFR 51.22(c). Therefore, in accordance with 10 CFR 51.22(b), an environmental impact statement or environmental assessment is not required for the NRC staff's consideration of this exemption request.

IV. Conclusions

Accordingly, the Commission has determined that, pursuant to 10 CFR 50.12, the exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security. Also, special circumstances are present. Therefore, the Commission hereby grants SNC an exemption from 10 CFR 50.71(h)(1) to modify the requirement for the level 1 and level 2 PRA for VEGP Units 3 and 4 to cover those initiating events and modes for which RG 1.200, Rev. 2, endorses standards.

Dated at Rockville, Maryland, this 26th day of October 2018.

For the Nuclear Regulatory Commission.

Michael D. McCoppin,

Deputy Director (Acting), Division of Licensing, Siting, and Environmental Analysis, Office of New Reactors.

[FR Doc. 2018–23840 Filed 10–31–18; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 52–025 and 52–026; NRC–2008–0252]

Southern Nuclear Operating Company, Inc.; Vogtle Electric Generating Plant, Units 3 and 4, Equipment Survivability Assessment

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption and combined license amendment; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is granting an exemption to allow a departure from the certification information of Tier 1 of the generic design control document (DCD) and is issuing License Amendment Nos. 139 and 138 to Combined Licenses (COLs), NPF–91 and NPF–92. The COLs were issued to Southern Nuclear Operating Company, Inc., Georgia Power Company, Oglethorpe Power Corporation, MEAG Power SPVM, LLC, MEAG Power SPVJ, LLC, MEAG Power SPVP, LLC, and the City of Dalton, Georgia (collectively SNC); for construction and operation of the Vogtle Electric Generating Plant (VEGP) Units 3 and 4, located in Burke County, Georgia.

The granting of the exemption allows the changes to Tier 1 information asked for the amendment. Because the acceptability of the exemption was determined in part by the acceptability of the amendment, the exemption and amendment are being issued concurrently.

DATES: The exemption and amendment were issued on August 24, 2018.

ADDRESSES: Please refer to Docket ID NRC–2008–0252 when contacting the NRC about the availability of information regarding this document. You may access information related to this document, which the NRC possesses and is publicly available, using any of the following methods:

- *Federal Rulemaking Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2008–0252. Address questions about *Regulations.gov* Docket IDs to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly available documents online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if that document is available in ADAMS) is provided the first time that a document is referenced. The request for the amendment and exemption was submitted by letter dated April 6, 2018 (ADAMS Accession No. ML18096B463).
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Paul Kallan, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2809; email: *Paul.Kallan@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC is granting exemptions from paragraph B of section III, ''Scope and Contents,'' of appendix D, ''Design

Certification Rule for the AP1000,'' to part 52 of title 10 of the *Code of Federal Regulations* (10 CFR), and issuing License Amendment Nos. 139 and 138 to COLs, NPF–91 and NPF–92, to SNC. The exemptions are required by paragraph A.4 of section VIII, ''Processes for Changes and Departures,'' appendix D, to 10 CFR part 52 to allow SNC to depart from Tier 1 information. With the requested amendment, SNC proposes changes to the Updated Final Safety Analysis Report (UFSAR) in the form of departures from the incorporated plant-specific Design Control Document (DCD) Tier 2 information and related changes to the VEGP Units 3 and 4 COL and COL Appendix C (and corresponding plant-specific DCD Tier 1) information. Specifically, the requested amendment includes changes to the equipment survivability assessment requirements associated with hydrogen burns during beyond design basis accidents as described in the licensing basis documents, including COL Condition 2.D(12)(g)9 and plant-specific Tier 1 Sections 2.2.3 and 2.3.9.

Part of the justification for granting the exemptions was provided by the review of the amendments. Because the exemption is necessary in order to issue the requested license amendment, the NRC granted the exemptions and issued the amendments concurrently, rather than in sequence. This included issuing a combined safety evaluation containing the NRC staff's review of both the exemption request and the license amendment. The exemptions met all applicable regulatory criteria set forth in sections 50.12, 10 CFR 52.7, and Section VIII.A.4 of appendix D to 10 CFR part 52. The license amendments were found to be acceptable as well. The combined safety evaluation is available in ADAMS under Accession No. ML18207A482.

Identical exemption documents (except for referenced unit numbers and license numbers) were issued to SNC for VEGP Units 3 and 4 (COLs NPF–91 and NPF–92). The exemption documents for VEGP Units 3 and 4 can be found in ADAMS under Accession Nos. ML18207A476 and ML18207A477, respectively. The exemption is reproduced (with the exception of abbreviated titles and additional citations) in Section II of this document. The amendment documents for COLs NPF–91 and NPF–92 are available in ADAMS under Accession Nos. ML18207A478 and ML18207A480, respectively. A summary of the amendment documents is provided in Section III of this document.

II. Exemption

Reproduced below is the exemption document issued to VEGP Units 3 and Unit 4. It makes reference to the combined safety evaluation that provides the reasoning for the findings made by the NRC (and listed under Item 1) in order to grant the exemption:

1. In a letter dated April 6, 2018, SNC requested from the Commission an exemption from the provisions of 10 CFR part 52, appendix D, section III.B, as part of license amendment request (LAR) 18–001, ''Equipment Survivability Assessment.''

For the reasons set forth in Section 3.1, ''Evaluation of Exemption,'' of the NRC staff's safety evaluation, which can be found in ADAMS under Accession No. ML18207A482, the Commission finds that:

A. The exemption is authorized by law;

B. The exemption presents no undue risk to public health and safety;

C. The exemption is consistent with the common defense and security;

D. Special circumstances are present in that the application of the rule in this circumstance is not necessary to serve the underlying purpose of the rule;

E. The special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the exemption; and

F. The exemption will not result in a significant decrease in the level of safety otherwise provided by the design.

2. Accordingly, SNC is granted an exemption from the certified DCD Tier 1 information, with corresponding changes to appendix C of the Facility Combined License as described in the licensee's request dated April 6, 2018. This exemption is related to, and necessary for, the granting of License Amendment Nos. 139 (Unit 3) and 138 (Unit 4), which is being issued concurrently with this exemption.

3. As explained in Section 5.0, ''Environmental Consideration,'' of the NRC staff's safety evaluation (ADAMS Accession No. ML18207A482), this exemption meets the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22(c)(9). Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment needs to be prepared in connection with the issuance of the exemption.

4. This exemption is effective as of the date of its issuance.

III. License Amendment Request

By letter dated April 6, 2018, SNC requested that the NRC amend the COLs for VEGP, Units 3 and 4, COL Nos. NPF–91 and NPF–92. The proposed amendment is described in Section I of this **Federal Register** notice.

The Commission has determined for these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR chapter I, which are set forth in the license amendment.

A notice of consideration of issuance of amendment to facility operating license or combined license, as applicable, proposed no significant hazards consideration determination, and opportunity for a hearing in connection with these actions, was published in the **Federal Register** on May 22, 2018 (83 FR 23738). No comments were received during the 30-day comment period.

The Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments.

IV. Conclusion

Using the reasons set forth in the combined safety evaluation, the staff granted the exemption and issued the amendment that SNC requested on April 6, 2018. The exemptions and amendments were issued on August 24, 2018, as part of a combined package to SNC (ADAMS Accession No. ML18207A488).

Dated at Rockville, Maryland, this 29th day of October, 2018.

For the Nuclear Regulatory Commission.

Jennifer L. Dixon-Herrity,

Chief, Licensing Branch 4, Division of Licensing, Siting, and Environmental Analysis, Office of New Reactors.

[FR Doc. 2018–23869 Filed 10–31–18; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84494; File No. SR–CHX–2018–05]

Self-Regulatory Organizations; Chicago Stock Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Reflect Name Changes of the Exchange and its Direct Parent Company and To Amend Certain Corporate Governance Provisions

October 26, 2018.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on October 18, 2018, the Chicago Stock Exchange, Inc. (''CHX'' or ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Amended and Restated Certificate of Incorporation of the Exchange (''Exchange Certificate''), the Amended and Restated Bylaws of the Exchange (''Exchange Bylaws''), the Second Amended and Restated Certificate of Incorporation of the Exchange's parent CHX Holdings, Inc. (''Holdings'' and, such certificate, the ''Holdings Certificate''), the Second Amended and Restated Bylaws of Holdings (''Holdings Bylaws''), the rules of the Exchange (''Rules'') and the fee schedule of the Exchange (''Fee Schedule'') to (1) reflect a name change of the Exchange to ''NYSE Chicago, Inc.'' and a name change of Holdings to ''NYSE Holdings, Inc.''; (2) harmonize certain provisions thereunder with similar provisions in the governing documents of the national securities exchange affiliates of the Exchange and its parent companies; and (3) make clarifying and updating changes. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

(1) Generally

The Exchange proposes to amend the Exchange Certificate, Exchange Bylaws, Holdings Certificate, Holdings Bylaws, Rules and Fee Schedule to (1) reflect a name change of the Exchange to ''NYSE Chicago, Inc.'' and a name change of Holdings to ''NYSE Chicago Holdings, Inc.''; (2) harmonize certain provisions thereunder with similar provisions in the governing documents of the national securities exchange affiliates of the Exchange [4] and its parent companies; and (3) make clarifying and updating changes.

The Exchange and Holdings were recently acquired by NYSE Group, Inc. (''NYSE Group''), which in turn is indirectly wholly owned by NYSE Holdings LLC (''NYSE Holdings''). NYSE Holdings is a wholly owned subsidiary of Intercontinental Holdings, Inc. (''ICE Holdings''), which is in turn wholly owned by the Intercontinental Exchange, Inc. (''ICE'').[5] As a result of its acquisition, the Exchange became part of a corporate family including five separate registered national securities exchanges. Following the acquisition, the Exchange has continued to operate as a separate self-regulatory organization and continues to have rules, membership rosters and listings distinct from the rules, membership rosters and listings of the other NYSE Group Exchanges.

The Exchange believes it is important for each of the exchanges to have a consistent approach to corporate governance in certain matters, to simplify complexity and create greater consistency among the NYSE Group Exchanges.[6] Accordingly, in addition to implementing the proposed name changes and making clarifying and updating changes, the Exchange proposes to harmonize certain aspects of its corporate governance framework to the existing structure at the other NYSE Group Exchanges, particularly as it relates to board and committee structure, administration, and governance practices. Because the Exchange is a Delaware corporation, most of the proposed changes are based on the governing documents of NYSE National, which is also a Delaware corporation, and NYSE Arca, which is a Delaware non-stock corporation, as the most comparable NYSE Group Exchanges.[7]

The Exchange is not proposing any amendments to its ownership structure. Furthermore, the Exchange is not proposing any amendments to its trading rules at this time other than the minor technical amendments to implement the name change, as set forth below.

The name changes and other changes described herein would become operative upon the Exchange Certificate becoming effective pursuant to its filing with the Secretary of State of the State of Delaware.

In addition to the proposed changes to the Exchange Certificate, Exchange Bylaws, Holdings Certificate, Holdings Bylaws, Rules and Fee Schedule described below, the proposed rule change includes numerous non-substantive grammatical edits to conform existing language to the proposed language (*e.g.,* replacing ''a'' with ''an'' when referring to ''Exchange'' or adding or deleting articles such as ''the''). Such changes are not described in detail under this Section 3 but are marked in the respective Exhibit 5 documents.

(2) Name Changes of the Exchange and Holdings

The Exchange has determined that for marketing purposes it would be desirable to change the name of the Exchange to ''NYSE Chicago, Inc.'' and the name of Holdings to ''NYSE Chicago

[4] The Exchange has four registered national securities exchange affiliates: NYSE National Inc. (''NYSE National''), NYSE Arca, Inc. (''NYSE Arca''), New York Stock Exchange LLC (''NYSE''), NYSE America LLC (''NYSE American'' and together with the Exchange, NYSE National, NYSE Arca and NYSE, the ''NYSE Group Exchanges'').

[5] *See* Exchange Act Release No. 83635 (July 13, 2018), 83 FR 34182 (July 19, 2018) (SR–CHX–2018–004); *see also* Exchange Act Release No. 83303 (May 22, 2018), 83 FR 24517 (May 29, 2018) (SR–CHX–2018–004).

[6] *See* 83 FR 34182, 34187, *id.*

[7] The other NYSE Group Exchanges, NYSE and NYSE American, are limited liability companies organized under New York and Delaware limited liability company law, respectively.

Holdings, Inc.,'' so as to be stylistically consistent with the names of the other NYSE Group Exchanges.[8] The Exchange does not propose to change the name of its affiliated routing broker, CHXBD, LLC.

In connection with the name changes, the Exchange proposes the following amendments, as reflected in the Exhibit 5.

a. Exchange Certificate

The Exchange proposes to amend the Exchange Certificate as follows:

- Amend the title, first introductory paragraph and signature block to reflect that the proposed Exchange Certificate is the ''Second Amended and Restated Certificate of Incorporation'';
- Delete ''July 18, 2018'' from the signature block and replace a reference to ''CHICAGO STOCK EXCHANGE, INC.'' in Article FIRST with ''NYSE Chicago, Inc.''; and
- Replace a reference to ''CHX Holdings, Inc.'' under Article FOURTH with ''NYSE Chicago Holdings, Inc.''

b. Exchange Bylaws

The Exchange proposes to amend the Exchange Bylaws as follows:

- Amend the title to reflect that the proposed Exchange Bylaws are the ''Second Amended and Restated Bylaws of NYSE Chicago, Inc.'';
- Replace a reference to ''the Chicago Stock Exchange, Inc.'' under Article 1, Section 1 with ''NYSE Chicago, Inc.''; and
- Replace all references to ''CHX Holdings, Inc.'' under current Article X, Section 2 (proposed Article IX, Section 2) [9] with ''NYSE Chicago Holdings, Inc.''

c. Holdings Certificate

The Exchange proposes to amend the Holdings Certificate as follows:

- Amend the title to reflect that the proposed Holdings Certificate is the ''Third Amended and Restated Certificate of Incorporation'';
- Adopt introductory paragraphs providing the current name of Holdings and stating that the Holdings Certificate was adopted and amended in accordance with specific provisions of the General Corporation Law of the State of Delaware (''DGCL'').
- Replace a reference to ''CHX Holdings, Inc.'' under Article I of the proposed Holdings Certificate with ''NYSE Chicago Holdings, Inc.'';
- Adopt Article XIV (Effective Time) to provide the effective date and time of the proposed Holdings Certificate; and
- Insert a signature block for the execution of the proposed Holdings Certificate.

d. Holdings Bylaws

The Exchange proposes to amend the Holdings Bylaws as follows:

- Amend the title to reflect that the proposed Holdings Bylaws are the ''Third Amended and Restated Bylaws of NYSE Chicago Holdings, Inc.'' and
- Replace a reference to ''CHX Holdings, Inc.'' under Article I, Section 1.1 with ''NYSE Chicago, Holdings, Inc.''

e. Rules

The Exchange proposes to amend the Rules as follows: [10]

- Replace references to ''the Chicago Stock Exchange, Inc.'' ''Chicago Stock Exchange, Inc.'' or ''the Chicago Stock Exchange, Incorporated'' with ''NYSE Chicago, Inc.'' in the title of the Rules and under Article 1, Rules 1(f), 1(g) and 1(k); paragraph .01 of the Interpretations and Policies of Article 7, Rule 4; and paragraph .02(g) of the Interpretations and Policies of Article 22, Rule 2. Similarly, the Exchange proposes to delete ''Chicago Stock'' before ''Exchange'' in Article 7, Rule 6(c)(1)(H) and paragraph .01(a) of the Interpretations and Policies of Article 8, Rule 16, and to replace ''Chicago Stock Exchange'' with ''NYSE Chicago'' in paragraph .01(h) of the Interpretations and Policies of Article 22, Rule 2.
- Replace references to ''CHX Holdings, Inc.'' with ''NYSE Chicago Holdings, Inc.'' under Article 1, Rule 1(h); and Article 3, Rules 18 and 20.
- Replace a reference to ''CHX Holdings'' with ''NYSE Holdings'' under Article 1, Rule 1(h).
- Replace references to ''CHX'' with ''NYSE Chicago'' under Article 1, Rules 1(g) and 1(h).
- Replace references to ''CHX'' with ''Exchange'' (defined under proposed Article 1, Rule 1(k)) under Article 1, Rules 1(ll); 2(b)(1)(C) (resulting in the current ''CHX Only'' order execution modifier being renamed ''Exchange Only''), 2(b)(1)(D), 2(c)(1)(A) and 2(c)(2); Article 5, Rule 3(a)(11); paragraph .03 of the Interpretations and Policies of Article 9, Rule 17; Article 17, Rules 3, 5(a), 5(b), 5(c)(3)(A) (resulting in the current ''*Quote@CHX*'' Brokerplex order type being renamed ''*Quote@Exchange*''), 5(c)(3)(B) (resulting in the current ''*Reprice@CHX*'' Brokerplex order type being renamed ''*Reprice@Exchange*''), 5(g) and 6(a); Article 18, Rule 1(b)(2)(D)(i); Article 20, Rules 2A(b)(2), 2A(c)(4), 5(a)(2), 6(d)(2), 8(b)(6), 8(d)(3), 8(d)(4)(A), 9(c), 13(a), paragraph .02 of 13(a), 13(b), paragraph .03 of 13(b) and 13(c).

As the Exchange will no longer be referred to as ''CHX'' under the proposed Rules, the Exchange proposes to amend Article 1, Rule 1(k), defining ''Exchange,'' to delete the last sentence providing ''[t]he Exchange may also be referred to in these Rules as the 'CHX'.''

- Replace references to ''CHX book'' or ''CHX Book'' with ''book'' (as ''Book'' is not defined under the Rules) under Article 1, Rules 2(a)(2), 2(b)(1)(D), 2(c)(1)(B), 2(c)(2), 2(c)(3), 2(g)(1) and 2(h)(3); Article 16, Rule 4(d)(1); Article 18, Rules 1(b)(2), 1(b)(3), 1(b)(4), 1(b)(5), 1(c)(1), 1(c)(2) and 1A(b); Article 19, Rule 3(a)(3); and Article 20, Rules 2A(a)(4)(ii), 2A(c)(3)(A), 8(b), 8(d)(1), 8(d)(4)(B) and 8(f)(1).
- Replace references to the ''CHX Routing Services'' with ''Routing Services'' under Article 1, Rule 2(h)(1)(A)(iv); Article 18, Rules 1(b)(2)(E), 1A(c)(2); Article 19, Rules 1, 2 and 3; and Article 20, Rules 8(a) and 12(a).
- Replace references to ''CHX Rules'' and ''CHX rules'' with ''Rules'' (defined under Article 1, Rule 1(x)) under Article 1, Rules 1(pp), 1(rr) and 2; paragraph .03(b) of the Interpretations and Policies of Article 9, Rule 17; Article 15, Rule 1(a); Article 16, Rules 1(d), 2(e)(1) and 4(a); Article 17, Rules 5(b), 5(d) and 7(b); Article 18, Rule 1(c)(1)(C); Article 19, Rule 3(a); Article 20, Rules 1, 2A(b)(2)(A), 9(c), 11(c)(4); and Article 23, Rule 13(a)(3).
- Replace a reference to ''CHX rule'' with ''Rule'' under Article 15, Rule 1(a).
- Replace all references to ''CHX Matching System'' with ''Matching System'' under Article 1, Rule 2(c)(1); Article 17, Rules 5(a), 5(c)(3)(A) and 5(c)(3)(B); and in the title of Article 20. Correspondingly, amend Article 1, Rule 1(z) defining ''Trading Facilities'' to include ''Matching System'' as an example of a Trading Facility. [11]
- Replace references to ''CHX Book Feed'' with ''Book Feed'' (resulting in the ''CHX Book Feed'' service being renamed ''Book Feed'') under Article 4, Rule 1 and Article 18, Rule 1(b)(1)(B).

[8] *See supra* note 4.

[9] As described below, the Exchange proposes to eliminate Article IX of the current Exchange Bylaws, thereby resulting in Article X of the current Exchange Bylaws becoming Article IX of the proposed Exchange Bylaws.

[10] The Exchange will submit subsequent rule filings as necessary to make any technical corrections to proposed rule changes that are pending as of the date of submission of this filing and approved by the Commission thereafter.

[11] In previous rule filings, the Exchange explained that the Matching System is a part of the Exchange's ''Trading Facilities,'' which is defined under Article 1, Rule 1(z) of the Rules. *See e.g.,* Exchange Act Release No. 34–81315 (August 4, 2017), 82 FR 37479, 37484 (August 10, 2017) (SR–CHX–2017–12).

• Replace a reference to ''CHX Participant Firm'' with ''Participant Firm'' (defined under Article 1, Rule 1(s)) under paragraph .03 of the Interpretations and Policies under Article 17, Rule 3.

• Replace references to ''CHX Participant'' with ''Exchange Participant'' under Article 20, Rule 13, as the term ''Participant'' is a defined term under both Article 1, Rule 1(s) (referring to members of the Exchange) and the Regulation NMS Plan to Implement a Tick Size Pilot Program [12] (''Tick Size Plan'') (referring to certain national securities exchanges as a group). Utilizing the term ''Exchange Participant'' under Article 20, Rule 13, as opposed to ''Participant,'' would ensure that Tick Size Plan Rules applicable to Exchange members will continue to be clearly distinguished from those applicable to the Exchange. However, under Article 4, Rule 1(a), the Exchange proposes to replace ''CHX Participant'' with ''Participant,'' as the rule is not related to the Tick Size Plan.

• Replace references to ''CHX Connect'' with ''Connect'' (resulting in the ''CHX Connect'' service being renamed ''Connect'') under Article 4, Rule 2.

• Replace references to ''CHX Article'' with ''Article'' under Article 9, Rule 17 and Article 16, Rule 4(d)(2).

• Replace references to ''CHX Market Maker Trading Account'' with ''Market Maker Trading Account'' under Article 16, Rule 1(f).

• Replace references to ''CHX-registered Institutional Broker'' with ''Institutional Broker'' (defined under Article 1, Rule 1(n)) under Article 17, Rule 5(a).

f. Fee Schedule

The Exchange proposes to amend the Fee Schedule as follows:

• Replace a reference to ''the Chicago Stock Exchange, Inc.'' ''NYSE Chicago, Inc.'' in the title of the Fee Schedule.

• Delete references to obsolete ''operative dates'' under Sections A and C.

• Replace references to ''CHX'' with ''Exchange'' under Sections C, D.1 and D.2(b).

• Replace references to the ''CHX Routing Services'' with ''Routing Services'' under Sections E.6, E.8(c) and E.9(c).

• Replace a reference to ''non-CHX executed trades'' with ''away executed trades'' under Section E.7(a).

• Replace a reference to ''a CHX-registered Institutional Broker'' with ''an Institutional Broker'' under Section E.7(a).

• Replace a reference to ''CHX Connect'' with ''Connect'' under Section L.

• Replace a reference to ''CHX Book Feed'' with ''Book Feed'' under Section M.

• Replace references to ''CHX Article'' with ''Article'' under Section P and the subtitle to the Minor Rule Violation Plan.

(3) Amendments to Certain Exchange Corporate Governance Provisions

In addition to the name changes, the proposed changes are designed to align the Exchange's corporate governance framework to the existing structure at the other NYSE Group Exchanges, particularly as it relates to board and committee structure, administration, and governance practices, and to make certain clarifying and updating changes. The proposed Exchange Certificate, Exchange Bylaws and Rules reflect the expectation that the Exchange will be operated with a governance structure substantially similar to that of other NYSE Group Exchanges, primarily NYSE National and NYSE Arca.

The proposed amendments described below are primarily based on the Amended and Restated Certificate of Incorporation of NYSE National, Inc. (''NYSE National Certificate''), the Fifth Amended and Restated Bylaws of NYSE National, Inc. (''NYSE National Bylaws''), and the Amended and Restated NYSE Arca, Inc. (''NYSE Arca Bylaws''). In addition, the amendments to the indemnification provisions are based on the Eighth Amended and Restated Bylaws of Intercontinental Exchange, Inc. (''ICE Bylaws'') and the Sixth Amended and Restated Bylaws of Intercontinental Exchange Holdings, Inc. (''ICE Holdings Bylaws''). Finally, the proposed clarification and updating changes are described below.

a. Exchange Certificate

Introductory Paragraphs

The Exchange proposes to make non-substantive changes to the introductory paragraphs. It would amend the first introductory paragraph to insert ''228,'' between the ''Section'' and ''242,'' as Article NINTH was adopted in a manner consistent with Section 228 of the DGCL.[13] The Exchange notes that the introductory paragraph of the NYSE National Certificate also refers to Sections 228, 242 and 245 of the DGCL.[14] The Exchange also proposes to amend the third introductory paragraph to be similar to the second introductory paragraph of the NYSE National Certificate, so that it provides that pursuant to Sections 242 and 245 of the DGCL, the proposed Exchange Certificate hereby amends and restates the current Exchange Certificate in its entirety.

Articles Third and Ninth

In a non-substantive change, the Exchange proposes to amend Articles THIRD and NINTH to replace references to ''Delaware'' with ''the State of Delaware,'' such that all references to the ''state of Delaware'' under the proposed Exchange Certificate are consistent with the NYSE National Certificate.

Article Fifth

Current Article FIFTH includes requirements related to the composition of the board of directors of the Exchange (''Board'' and each member of the Board a ''Director''). The Exchange proposes to amend Article FIFTH as follows.

Proposed paragraph (a). Current paragraph (a) (Authority) provides that the business and affairs of the Exchange shall be managed by the Board pursuant to the Rules and the Exchange Bylaws and that the Board has the authority to establish committees of the Board and to delegate authority to such committees, subject to the Rules and the Exchange Bylaws.

The Exchange proposes to amend paragraph (a) to be similar to Article FIFTH(a) of the NYSE National Certificate and provide additional clarity regarding board elections. Notably, proposed paragraph (a) omits provisions related to the creation of Board committees, as such provisions would be addressed in Article IV of the proposed Exchange Bylaws, as described below. Proposed paragraph (a) also adopts additional language related to the nomination of Directors for election that is similar to language under Article II, Section 2(f) of the proposed Exchange Bylaws. Therefore, proposed Article FIFTH(a) provides as follows: [15]

General. The governing body of the Exchange shall be its Board of Directors which shall exercise all powers conferred to it by the laws of the State of Delaware. In furtherance of and not in limitation of the powers conferred by statute, the Board of Directors is expressly authorized to adopt the

[12] *See* Exchange Act Release No. 74892 (May 6, 2015), 80 FR 27514 (May 13, 2015).

[13] *See* Del. Code tit. 8, § 228.

[14] *See* Del. Code tit. 8, §§ 228, 242, and 245.

[15] The full text of the Exchange Certificate and Exchange Bylaws are set forth in Exhibits 5A and 5B, respectively. The Exchange notes that the Exchange Certificate and Exchange Bylaws use the term ''Corporation'' instead of ''Exchange.'' To avoid possible confusion, excerpts of the Exchange Certificate and Exchange Bylaws noted in this proposed rule change use the term ''Exchange.''

bylaws and the rules of the Exchange and to amend or repeal any provision thereof subject to such conditions as the bylaws or rules may provide. Directors shall be elected by the stockholders of the Exchange. Elections of directors of the Exchange need not be by written ballot unless the bylaws so provide. Except as otherwise provided in the Bylaws or the rules, the stockholders shall nominate directors for election at the annual meeting of the stockholders. Such nominations shall comply with the Exchange's rules and the Bylaws.

Deleting Current Paragraphs (b)–(e) and (g). The Exchange proposes to delete current paragraphs (b) (Number and Composition of Directors), (c), (d) (Terms) and (e) (Election and Qualification of Directors) as redundant of identical provisions found under Article II, Section 2(a), (b), (e) and (c) of the proposed Exchange Bylaws, respectively. The Exchange also proposes to delete current paragraph (g) (Vacancies) as redundant of Article II, Section 5 of the proposed Exchange Bylaws.

Proposed paragraph (b). Current paragraph (f) (Removal of Directors) provides that no Director may be removed from office by a vote of the stockholders at any time except for cause and defines ''cause'' as (i) a breach of a director's duty of loyalty to the Corporation or its stockholders, (ii) acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) actions resulting in liability under Section 174 of the General Corporation Law of Delaware, or (iv) transactions from which a director derived an improper personal benefit. Any director may be removed for cause by the holders of a majority of the shares of capital stock then entitled to be voted at an election of directors.

The Exchange proposes to move current paragraph (f) to proposed paragraph (b) and to amend the provision to be similar to Article FIFTH(b) of the NYSE National Certificate by permitting any Director to be removed from office by a vote of the stockholders at any time with or without cause, except that Non-Affiliated Directors, as defined under Article II, Section 2(a) of the proposed Exchange Bylaws, may only be removed for cause. The Exchange proposes to amend the definition of ''cause'' to provide that the list set forth in the provision is inclusive.[16] Consistent with the proposed changes in Articles THIRD and NINTH, the Exchange also proposes to replace a reference to ''Delaware'' with ''the State of Delaware.''

Proposed paragraph (c). Proposed paragraph (c) provides that the stockholder shall have authority to fix compensation of all directors for services to the Corporation as directors, officers or otherwise, which is similar to the last sentence under Article III, Section 3.15 of the NYSE National Bylaws.

Article Seventh

Current Article SEVENTH provides that the Board shall have the power to adopt, amend or repeal the Exchange Bylaws and the Rules and that the Exchange Bylaws may also be amended or repealed, or new bylaws may be adopted, by action taken by the stockholders of the Exchange.

The Exchange proposes to amend Article SEVENTH[17] by adding language that provides that before any amendment to, alteration or repeal of any provision of the Exchange Bylaws under this Article SEVENTH shall be effective, those changes shall be submitted to the Board and if the same must be filed with or filed with and approved by the Commission the proposed changes to the Exchange Bylaws shall not become effective until filed with or filed with and approved by the Commission, as the case may be. The Exchange does not propose to adopt additional language found under Article SEVENTH of the NYSE National Certificate requiring changes to the bylaws of the NYSE National be effected in compliance with Section 19 of the Exchange Act, as it would be redundant of Article VII, Sec. 1 of the proposed Exchange Bylaws, which requires that any amendments to the Exchange Bylaws be filed with or filed with and approved by the Commission before becoming effective.

Article Eighth

Proposed Article EIGHTH. Current paragraph (a) permits the Exchange to provide indemnification to certain persons. The Exchange now proposes to delete paragraph (a) in its entirety as it is duplicative of the indemnification provision in Article VI, Section 1 of the Exchange Bylaws and so unnecessary to include here.

Current paragraph (b) (Limitation of Liability) provides that to the fullest extent of the DGCL, no Director shall be liable to the Exchange or its stockholders for monetary damages for breach of fiduciary as a Director, except where such liability arises as a result of a violation of the federal securities laws.

The Exchange proposes to amend current paragraph (b) to conform to Article EIGHTH of the NYSE National Certificate.

Article Eleventh

Current Article ELEVENTH permits the Exchange to effect amendments to the Exchange Certificate and requires any proposed change to the Exchange Certificate be approved by the Board and by a majority of the stockholders of the Exchange present in person or by proxy at the meeting of the stockholders at which the amendment is submitted.

To better align current Article ELEVENTH with Article ELEVENTH of the NYSE National Certificate, the Exchange proposes to amend Article ELEVENTH to (1) modify the stockholder approval requirement to require a proposed amendment to the Exchange Certificate be approved by a majority of the stockholders of the Exchange, as opposed to the majority of the stockholders present in person or by proxy at the meeting of stockholders at which the amendment is submitted; and (2) clarify that any changes to the Exchange Certificate must be approved by, or filed with, the Commission, in compliance with Section 19 of the Exchange Act, and must be approved by the Board, before such changes become effective. The first proposed change is consistent with Section 242(b) of the DGCL, which provides, among other things, that amendments to the certificate of incorporation that require shareholder approval be approved by ''a majority of the outstanding stock entitled to vote thereon, and a majority of the outstanding stock of each class entitled to vote thereon as a class,''[18] as opposed to a majority present at a meeting. The proposed change is also consistent with Article ELEVENTH of the NYSE National Certificate, which

[16] *See* Eighth Amended and Restated Bylaws of Cboe BZX Exchange, Inc. (''Cboe BZX Bylaws''), Section 3.4(c) (providing that ''[n]o Representative Director may be removed from office by a vote of the stockholders at any time except for cause, which shall *include, but not limited to,* (i) a breach of a Representative Director's duty of loyalty to the Corporation or its stockholders, (ii) acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) transactions from which a Representative Director derived an improper personal benefit, or (iv) a failure of a Representative Director to be free from a statutory disqualification (as defined in Section 3(a)(39) of the Act)'') (emphasis added). *See also* NYSE Operating Agreement, Article II, Section 2.03(l) (providing that cause ''shall include, without limitation, the failure of [a] Director to be free of any statutory disqualification . . .'') and NYSE American Operating Agreement, Article II, Section 2.03(l) (same).

The Exchange understands that NYSE National expects to propose the same definitional change to Article FIFTH(b) of the NYSE National Certificate in a separate filing with the Commission.

[17] *See* NYSE National Certificate, Article SEVENTH.

[18] Del. Code tit. 8, § 242(b).

requires that any amendment to the NYSE National Certificate be effected in a manner prescribed at the time by statute (*e.g.,* Section 242(b) of the DGCL).

b. Exchange Bylaws

Article 1 (Officers; Registered Agent)

Proposed Section 1. Current Section 1 (Registered Office) provides that the registered office of the Exchange in the State of Delaware shall be at such location within the State of Delaware as shall from time to time be determined by the Board.

In an administrative change, the Exchange proposes to amend Section 1 to be similar to Article II, Section 2.1 of the NYSE National Bylaws. Specifically, proposed Section 1 adopts additional language that provides that the registered agent of the Exchange in the State of Delaware shall be such person or entity as shall from time to time be determined by the Board. The Exchange would make conforming edits to the title of Section 1.

Article II (Directors)

Proposed Section 1. Current Section 1 (Powers) provides that the business and affairs of the Exchange shall be managed by the Board, except as otherwise delegated to committee(s) of the Board pursuant to the Exchange Bylaws or Rules. It does not address the Board's powers in relation to the Exchange Act or any individual, corporation, partnership or other entity that holds a permit issued by the Corporation to trade securities on the market operated by the Corporation (each, a ''Participant'').

The Exchange proposes to amend Section 1 to be substantially similar to Article III, Section 3.1 of the NYSE National Bylaws, adding the definitions of ''rules,'' ''Exchange Act,'' and ''Participant,'' which are not previously defined.[19] The revised provision would provide as follows:

The business and affairs of the Exchange shall be managed by its Board of Directors. The Board of Directors, acting in accordance with the terms of these bylaws and the rules of the Exchange (''rules''), shall be vested with all powers necessary for the governing of the Exchange as an ''exchange'' within the meaning of the Securities Exchange Act of 1934, as amended (the ''Exchange Act''), the regulation of the business conduct of any individual, corporation, partnership or other entity that holds a permit issued by the Exchange to trade securities on the market operated by the Exchange (each, a ''Participant''), and the promotion of the welfare, objects and purposes of the Exchange.

Proposed Section 2. Current Section 2 (Number, Term of Office and Qualifications) addresses the general composition of the Board and the terms of Directors, which were adopted at the time the Exchange was acquired by ICE and are substantially similar to the requirements under the NYSE National Bylaws and NYSE Arca Bylaws.[20] None of the proposed changes to Section 2 are substantive.

Proposed Section 2 maintains the substance of current Section 2. However, to further align terminology used within the Exchange Certificate with the other NYSE Group Exchanges,[21] the Exchange proposes to amend Section 2 to replace references to (1) ''STP Participant'' with ''Non-Affiliated'' under paragraph (a),[22] such that ''STP Participant Directors'' are thereafter referred to as ''Non-Affiliated Directors,'' and (2) ''shareholder'' with ''stockholders'' under paragraph (f). The Exchange also proposes to (1) replace a reference to the ''Securities Exchange Act of 1934, as amended ('Exchange Act')'' with ''Exchange Act'' under paragraph (a), as the shorthand term is already defined under proposed Article II, Section 1; (2) replace references to ''Bylaws'' with ''bylaws'' under paragraphs (b), (c) and (f), and (3) replace a reference to ''Exchange'' with ''Corporation'' under paragraph (f), as the shorthand term is already defined under Article 1, Section 1.[23]

The Exchange further proposes to amend the title of proposed Section 2 to ''General Composition and Term of Office,'' so as to be consistent with the titles of Section 3.2 (General Composition) and 3.3 (Terms of Office) of the NYSE National Bylaws.

Proposed Section 3. Current Section 3 (Nomination and Election) provides the nomination and election process for STP Participant Directors (renamed ''Non-Affiliated Directors'' [24]). None of the changes to Section 3 are substantive.

The Exchange proposes to maintain the current nomination and election process and to amend paragraph (a) to clarify that the Nominating Committee shall nominate Non-Affiliated Directors only. Such change would be consistent with Article FIFTH(a) of the proposed Exchange Certificate, which provides, in part, that, except as otherwise provided in the Exchange Bylaws (*i.e.,* proposed Section 3) or the Rules, the stockholders shall nominate Directors for election at the annual meeting of the stockholders.[25] The Exchange also proposes to move the second and third sentences of current paragraph (a) to proposed Article IV, Section 7, which provides the composition requirements for the Nominating Committee and defines ''Permit Holder representative,'' as described below.

In addition, the Exchange proposes to amend paragraph (b) to delete the second sentence defining ''Participant,'' as it is already defined under proposed Article 1, Section 1, and to delete paragraph (d), which provides that the Board shall appoint the Nominating Committee, as duplicative of proposed Article IV, Section 2, which provides that the Board will appoint all committees of the Board, as described below.

Proposed Section 4. Current Section 4 (Chairman) includes various requirements and responsibilities of the chairman of the Board (''Chairman'').

The Exchange proposes to amend Section 4 to be consistent with the first sentence of Article III, Section 3.5 of the NYSE National Bylaws.[26] First, it would specify that the chairman must be elected by majority vote. Second, the references to the Chief Executive Officer (''CEO'') of the Exchange would be deleted, in accordance with the changes made to the composition of the Board at the time the Exchange was acquired,[27] which no longer require that the CEO serve on the Board. The proposed change would be consistent with the governing documents of the other NYSE Group Exchanges, none of which place limitations on which director may be elected as chairman.[28]

[19] Exchange ''Participants'' are the equivalent of NYSE National ''ETP Holders.'' *See* Arca Bylaws, Section 3.01(b).

[20] *See* NYSE National Bylaws, Article III, Section 3.2 and 3.3; and NYSE Arca Bylaws, Article III, Section 3.02. *See* also 83 FR 34182, 34189, *supra* note 5.

[21] *See* Article II, Section 2.03(a) of the Eleventh Amended and Restated Operating Agreement of NYSE (''NYSE Operating Agreement''); Article II, Section 2.03(a) of the Eleventh Amended and Restated Operating Agreement of NYSE American (''NYSE American Operating Agreement''); NYSE Arca Bylaws, Article III, Section 3.02; and NYSE National Bylaws, Article III, Section 3.2.

[22] The Exchange proposes to replace all subsequent references to ''STP Participant'' with ''Non-Affiliated'' under proposed Article II, Sections 3 and 5.

[23] The Exchange proposes to replace all subsequent references to ''Exchange'' with ''Corporation'' under proposed Article II, Section 6; Article VII, Section 3; and Article X, Sections 1 and 2.

[24] *See supra* note 22.

[25] *See also* NYSE National Bylaws, Article III, Section 3.4 and NYSE Arca Bylaws, Article III, Section 3.02.

[26] *See also* Arca Bylaws Article 3.02(d).

[27] *See* 83 FR 34182, 34187, *supra* note 5.

[28] *See* NYSE National Bylaws, Article III, Section 3.5; and NYSE Arca Bylaws, Article III, Section 3.02(d). The NYSE Operating Agreement and NYSE American Operating Agreement do not address how their respective chairman will be elected, or who may serve.

The proposed changes to current Section 4(b) would conform it to the last two sentences of Article III, Section 3.5 of the NYSE National Bylaws. The proposed changes would eliminate language related to the appointment of members to Board committees, which is no longer required here, as it would be addressed in proposed Article IV, as described below. Therefore, proposed Section 4 provides as follows:

> The Board of Directors, acting through a vote of a majority of its directors, shall elect the Chairman of the Board from among the directors of the Corporation. Unless another director is appointed by the Board for such purpose in the Chairman's absence, the Chairman shall preside at all meetings of the stockholders and the Board. The Chairman shall also have such other duties, authority and obligations as may be given to him or her by these bylaws or by the Board of Directors.

Deleting Current Section 5. Current Section 5 (Vice Chairman) provides the requirements and responsibilities of the vice chairman of the Board (''Vice Chairman'').

The Exchange proposes to delete current Section 5 in its entirety.[29] The Exchange notes that none of the governing documents of the other NYSE Group Exchanges require the designation of a Vice Chairman.

Proposed Section 5. Current Section 6 (Vacancies) provides the requirements and procedures for filling vacancies on the Board.

In an administrative change, the proposed edits would eliminate the current requirement that the Chairman and Vice Chairman provide the Board with the names to fill vacancies on the Board no later than five business days before the relevant vote. Such proposed change would be consistent with the governing documents of the other NYSE Group Exchanges, none of which require such notice.[30]

Proposed Section 6. Current Section 7 (Participation in Meeting, Action or Proceeding) prohibits a Director from being disqualified from participating in any meetings by reason of having made a prior inquiry, examination or investigation of the subject under consideration and prohibits a Director from participating in the determination of any matter in which such Director is personally interested.

The Exchange proposes to eliminate the provision prohibiting the disqualification of a Director by reason of the Director having made prior inquiry, examination or investigation of the subject matter under consideration, as none of the governing documents of the other NYSE Group Exchanges have a similar provision. However, the Exchange proposes to maintain the prohibition of a Director from participating in the determination of any matter in which such Director is personally interested.

Proposed Section 7. Current Section 8 (Place of Meetings; Mode) provides requirements related to the place and mode of Board meetings.

The Exchange proposes to conform current Section 8 to Article III, Section 3.8 of the NYSE National Bylaws by eliminating reference to the Executive Committee, as it is redundant of the preceding language stating that members of the Board or any Board committee (which would include the Executive Committee) may attend a Board meeting.

Proposed Section 8. Current Section 9 (Regular Meetings) specifies that regular meetings may be held, with or without notice, at such time or place as the Board or Executive Committee specifies in a resolution.

The Exchange proposes that only the Board, not the Executive Committee, determine the time or place of its regular meetings. The change would be consistent with the governing documents of the other NYSE Group Exchanges, which do not provide that a committee may call a meeting of their respective board of directors.[31] In addition, the Exchange proposes an administrative change to eliminate the requirement for a Board resolution. The Exchange notes that the change would be consistent with the.governing documents of NYSE Arca, NYSE and NYSE American, which do not require a board resolution for meetings to be called.[32] The Exchange does not propose to amend the Exchange Bylaws' current provision stating that regular meetings of the Exchange Board may be held with or without notice.[33]

Proposed Section 9. Current Section 10 (Special Meetings), paragraph (a) permits special meetings of the Board to be called on two days' notice to each Director by the Chairman, the Vice Chairman or the CEO and shall be called by the Secretary upon the written request of any five Directors and paragraph (b) requires the person calling a special meeting to fix the time and place at which the meeting will be held, as well as additional requirements related to effecting adequate notice.

The Exchange proposes to amend paragraph (a) to reduce the minimum notice requirement from two days to one day and reduce the number of Directors' written requests required from five Directors to three Directors then in office. As such, proposed Section 9 is largely similar to Article III, Section 3.10(a) of the NYSE National Bylaws, except for minimum notice requirement of one day. The Exchange submits that reducing the minimum notice requirement to one day is reasonable as it facilitates the Board meeting quickly and notes that one day of notice would be consistent with the bylaws of other national securities exchanges.[34]

The Exchange also proposes to amend paragraph (b) by eliminating the requirement that the person calling the special meeting fix the time and place of the meeting, as proposed Article II, Section 7 already addresses the place and mode of Board meetings. Otherwise, the current requirements related to adequate notice are retained under proposed paragraph (b).

The changes to current Section 10 are administrative in nature.

Proposed Section 10. Current Section 11 (Quorum and Action by the Board) provides certain requirements related to quorum and action by the Board. Notably, current Section 11 (1) defines a ''quorum'' to be one-half of the number of directors then in office (including not less than 50 percent of the Public Directors [35]); (2) states that the act of a majority of the Directors

[29] Section numbers of the subsequent sections in Article III would be revised accordingly. The Exchange proposes to delete all subsequent references to ''Vice Chairman'' under proposed Article II, Sections 4, 5 and 10.

[30] *See* NYSE National Bylaws, Article III, Section 3.6; NYSE Arca Bylaws, Article III, Section 3.03; NYSE Operating Agreement, Article II, Section 2.03(l); and NYSE American Operating Agreement, Article II, Section 2.03(l).

[31] *See* NYSE Arca Bylaws Article III, Section 3.05; NYSE National Bylaws Article III, Section 3.9; NYSE Operating Agreement, Article II, Section 2.03(c); and NYSE American Operating Agreement, Article II, Section 2.03(c).

[32] *See* NYSE Arca Bylaws, Article III, Section 3.05; NYSE Operating Agreement, Article II, Section 2.03(c); and NYSE American Operating Agreement, Article II, Section 2.03(c).

[33] Similarly, NYSE National Bylaws Article III, Section 3.9 does not require notice for regular meetings. The Exchange expects NYSE National to propose that such provision be amended to remove the requirement for a resolution.

[34] *See* NYSE Operating Agreement, Article II, Section 2.03(c) (requiring 12 or 24 hours of notice, with the exception of mailed notice); NYSE American Operating Agreement, Article II, Section 2.03(c) (requiring 12 or 24 hours of notice, with the exception of mailed notice); Cboe BZX Bylaws, Section 3.11(requiring 24 hours of notice); Tenth Amended and Restated Bylaws of Cboe Exchange, Inc. (''Cboe Exchange Bylaws''), Section 3.11 (requiring 24 hours of notice); and Bylaws of Nasdaq, Inc., Article IV, Section 4.12 (requiring that notice be sent no later than ''the day before the day'' of the meeting, with the exception of mailed notice).

[35] Article II, Section 2 of the proposed Exchange Bylaws defines ''Public Directors'' as Directors who are persons from the public that are not affiliated with a broker-dealer in securities or employed by, or involved in any material business relationship with, the Exchange or its affiliates.

present at any meeting at which there is a quorum shall be the act of the Board of Directors except as may be otherwise specifically provided by statute, the Exchange Certificate, Exchange Bylaws or Rules; (3) provides that if at least 50 percent of the Public Directors are (a) present at or (b) have waived their attendance for a meeting after receiving an agenda prior to such meeting, the requirement that not less than 50 percent of the Public Directors be present to constitute the quorum shall be deemed satisfied; and (4) provides that if a quorum shall not be present at any meeting of the Board, a majority of the Directors present at the meeting may adjourn the meeting, without notice other than announcement at the meeting, until a quorum shall be present.

To better align proposed Section 10 with Article III, Section 3.11 of the NYSE National Bylaws, the Exchange proposes to

1. add an introductory sentence that provides that each Director shall be entitled to one vote;

2. amend the definition of ''quorum'' by

○ stating that the presence of a majority of the number of Directors then in office is required, rather than one half; and

○ (b) deleting the requirement that a quorum include no less than 50% of the Public Directors; and

3. amend the title to ''Voting; Quorum and Action by the Board.''

The proposed quorum provision would be consistent with the quorum provisions of the other NYSE Group Exchanges, which all provide that the presence of a majority of the directors constitutes a quorum, and do not impose requirements regarding the number of public directors.[36] In addition, the Exchange proposes to add language clarifying that the proposed quorum requirement would apply ''[e]xcept as otherwise required by law.'' [37] Correspondingly, the Exchange proposes to replace a reference to ''statute'' with the broader term ''law,'' as the later contemplates non-statutory law, such as common law.

Therefore, proposed Section 10 provides as follows:

Each director shall be entitled to one vote. Except as otherwise required by law, at all meetings of the Board of Directors, the presence of a majority of the number of directors then in office shall constitute a quorum for the transaction of business. The act of a majority of the directors present at any meeting at which there is a quorum shall be the act of the Board of Directors except as may be otherwise specifically provided by law, the certificate of incorporation, the bylaws or the rules. If a quorum shall not be present at any meeting of the Board of Directors, a majority of the directors present at the meeting may adjourn the meeting, without notice other than announcement at the meeting, until a quorum shall be present.

Proposed Section 13. Current Section 14 (Informal Action) permits the Board to take action without a meeting by written consent of all of the Directors and requires such written action be filed with the minutes of proceedings of the Board.

In an administrative change, the Exchange proposes to amend the provision to be substantially similar to Article III, Section 3.14 of the NYSE National Bylaws. Specifically, the title would be revised to state, ''Action in Lieu of Meeting'' [38] and the revised text would permit the Board and any committee of the Board to take action by written consent. Notably, as in the NYSE National provision, the proposed provision would include additional language clarifying that action by written consent may be taken by any committee of the Board and that such consent may be delivered in writing or by electronic transmission.[39]

Proposed Section 14. Current Section 15 (Compensation) provides that the directors may be paid their reasonable expenses, if any, of attendance at each meeting of the Board or a committee of the Board and that the Directors, irrespective of any personal interest of any of its members, shall have authority to fix the compensation of all directors for services to the Exchange.

The Exchange proposes to maintain the first sentence permitting Directors to be paid for their reasonable expenses. However, the Exchange proposes to move the provision related to the Board fixing Director compensation to Article FIFTH(c) of the proposed Exchange Certificate, as amended to be similar to the last sentence of Article III, Section 3.15 of the NYSE National Bylaws.

The changes to current Section 15 are administrative in nature.

Current Section 17. Current Section 17 (Interpretation of Bylaws and Rules) provides that the Board shall have the power to interpret the Exchange Bylaws and the Rules and any interpretation made by it shall be final and conclusive. The Exchange proposes to delete current Section 17 in its entirety as none of the other NYSE Group Exchanges have similar provisions in their respective governing documents.

Article III (Stockholders)

Article III contains provisions relating to the stockholders of the Exchange. With the exception of current Sections 5 and 14, the Exchange proposes to conform the provisions in Article III to Article IV of the NYSE National Bylaws, so as streamline provisions across the two NYSE Group Exchanges that have stockholders, for the sake of efficiency.[40] The proposed changes are administrative in nature, relating primarily to the administrative processes relating to the stockholder, and will have no material substantive effect on the current operations or governance of the Exchange.

Proposed Section 1. Current Section 1 (Annual Meetings) provides that the annual meeting shall be held on a business day in April each year, or on such other dates determined by the Board, for the purpose of electing Directors and the transaction of other business. The Exchange proposes to amend Section 1 to be substantially similar to Article IV, Section 4.1 of the NYSE National Bylaws. Notably, proposed Section 1 eliminates the requirement that the annual meeting be held in April. Proposed Section 1 also includes additional language that provides specific requirements for written notice to shareholders.[41] Unlike Article IV, Section 4.1 of the NYSE National Bylaws, proposed Section 1 includes an additional clarifying clause providing that the aforementioned written notice requirement shall apply ''[e]xcept as otherwise required by law.''

Proposed Section 2. Current Section 2 (Special Meetings) provides that the special meetings of the stockholders may be called by the Board or the CEO. The Exchange proposes to amend Section 2 to be similar to Article IV, Section 4.2 of the NYSE National Bylaws, except that proposed Section 2 includes additional language that provides that the written notice requirements shall apply ''[e]xcept as otherwise required by law.'' Notably, proposed Section 2 permits the Chairman, Board, CEO and the stockholders to call a special meeting;

[36] *See* NYSE Arca Bylaws Article III, Section 3.07; NYSE National Bylaws Article III, Section 3.11; NYSE Operating Agreement, Article II, Section 2.03(d); and NYSE American Operating Agreement, Article II, Section 2.03(d). The NYSE Arca provision requires that the majority be of the number of directors, while the other provisions cited require the majority be of the number of directors then in office.

[37] *See* DCGL Section 141(b).

[38] *See also* NYSE Arca Bylaws Article III, Section 3.09; NYSE Operating Agreement, Article II, Section 2.03(g); and NYSE American Operating Agreement, Article II, Section 2.03(g).

[39] *See also* NYSE Arca Bylaws Article III, Section 3.09.

[40] NYSE Arca is a non-stock corporation, and so has a member instead of stockholders. *See* NYSE Arca Bylaws, Article II, Section 2.01. Holdings is the sole stockholder of the Exchange.

[41] *See* Del. Code tit. 8, § 222.

includes written shareholder notice requirements consistent with Section 222 of the DGCL;[42] and limits the business transacted at special meetings to the purpose(s) stated in the written notice.

Deleting Current Sections 3 and 4. Current Section 3 (Place of Meetings) provides requirements for the place of stockholder meetings and current Section 4 (Notice of Meetings) provides notice requirements for stockholder meetings. Given that proposed Sections 1 and 2 provide time, place and notice requirements for stockholder meetings, as described above, current Sections 3 and 4 are obviated and the Exchange therefore proposes to delete these provisions entirely.[43]

Deleting Current Sections 6 and 7. Current Section 6 (Meeting of All Stockholders) permits notice of stockholder meetings to be waived if all stockholders agree in writing and current Section 7 (Record Dates) provides procedures related to record dates.

The Exchange notes that current Section 6 is redundant of proposed Section 4, which addresses waiver of notice, and the provisions under current Section 7 are redundant of Section 213 (Fixing date for determination of stockholders of record) of the DGCL. As such, the Exchange proposes to delete Sections 6 and 7 entirely.

Proposed Section 4. Current Section 8 (List of Stockholders) requires the Exchange officer who has charge of the stock ledger of the Exchange to prepare, at least 10 days before each meeting of stockholders a complete list of stockholders entitled to vote at the meeting.

In an administrative change, the Exchange proposes to amend the provision such that, as permitted by Section 219(a) of the DGCL, the ''Corporation,'' and not an officer of the Exchange specifically, is required to prepare the list of stockholders entitled to vote.[44] The Exchange proposes to make other non-substantive amendments so that proposed Section 4 is similar to Article IV, Section 4.3 of the NYSE National Bylaws.

Proposed Section 5. Current Section 9 (Quorum and Vote Required for Action) sets forth the quorum and voting requirements.

The Exchange proposes to amend the provision to be substantially similar to Article IV, Section 4.4 of the NYSE National Bylaws. Notably, proposed Section 9 eliminates the plurality vote requirement for Directors and establishes a majority vote requirement for all business brought before the stockholders, except as otherwise required by law or the Exchange Certificate.

Proposed Section 6. Current Section 10 (Proxies) provides that each stockholder entitled to vote at a meeting of the stockholders may authorize another person or persons to act for the stockholder by proxy and provides other requirements related to the proxies generally.

The Exchange proposes to amend the provision to be substantially similar to Article IV, Section 4.5 of the NYSE National Bylaws and to amend the title to state, ''Voting of Shares; Proxies.'' Notably, proposed Section 6 is largely similar to current Section 10, except that proposed Section 6 additionally provides that each stockholder of the Exchange at each meeting of the stockholders is entitled to one vote in person or by proxy for each share of capital stock having voting power held by such stockholder.

Deleting Current Sections 11–13. Current Section 11 (Voting Shares) provides that each share having voting power is entitled to one vote, current Section 12 provides that business at a meeting of the stockholders may be decided by voice vote unless the presiding officer orders voting by ballot and current Section 13 permits the presiding officer at a meeting of the stockholders to appoint one or more inspectors to take certain actions at the meeting.

The Exchange proposes to delete current Section 11 as redundant of proposed Section 6. The Exchange also proposes to delete current Sections 12 and 13 as they are not necessary as an administrative matter. There are no similar provisions under the NYSE National Bylaws.

Proposed Section 7. Current Section 14 (Informal Action) permits stockholder action to be taken by written consent and provides certain requirements related to such written consent.

The Exchange proposes to amend the provisions to permit stockholder action to be taken by written consent and to the extent provided by the DGCL, but only if the matter to be voted upon were approved by the Board and the Board had directed that the matter be brought before the stockholders. The Exchange also proposes to amend the title to read ''Action in Lieu of Meeting.''

Article IV (Committees)

Current Article IV provides requirements related to committees of the Board. The Exchange proposes to amend Article IV to eliminate the requirement that the Exchange maintain Audit, Compensation and Finance Committees, as matters that would normally be considered by those committees will be addressed by the Board or upstream by the audit and compensation committees of ICE. Therefore, proposed Article IV is similar to Article V of the NYSE National Bylaws, streamlining provisions across NYSE Group Exchanges, except that the Exchange will maintain an Executive Committee and Judiciary Committee, as Article 12 of the Rules (Disciplinary Matters and Trial Proceedings) require that such committees exist, as described below.

In addition, the Exchange proposes to incorporate provisions regarding each Board committee (the Regulatory Oversight Committee (''ROC''), Nominating Committee, and Executive Committee) into the Bylaws, ensuring that such committees are established in the governing documents of the Exchange.

Proposed Section 1. Current Section 1 (Number of Committees) provides that the committees of the Exchange shall consist of an Executive Committee, a Nominating Committee, an Audit Committee, a Compensation Committee, a Regulatory Oversight Committee (''ROC''), a Finance Committee, a Judiciary Committee and such other committees as may be provided in the bylaws or rules or as may be from time to time established by the Board of Directors.

Proposed Section 1 maintains the requirements of current Section 1, except that it omits references to the Audit, Compensation and Finance Committees, for the reasons noted above.

Proposed Section 2. Current Section 2 (Appointment of Committees) provides the requirements for the appointment of the committees.

The Exchange proposes to amend Section 2 to be similar to Article V, Section 5.2 of the NYSE National Bylaws and to amend the title to state, ''Appointment; Vacancies; and Removal.'' Specifically, proposed paragraph (a) is substantially similar to Article V, Section 5.2 of the NYSE National Bylaws and provides that the Board shall appoint, consistent with the Exchange Bylaws, the members of all committees of the Board, and the Board may, at any time, with or without cause, remove any member of a committee so

[42] *See* Del. Code tit. 8, § 222.

[43] Section numbers of the subsequent sections in Article IV would be revised accordingly.

[44] Del. Code tit. 8, § 219(a).

appointed, unless otherwise provided therein.

Proposed paragraph (b) provides that any vacancy occurring in a committee shall be filled by the Board, consistent with the DGCL.[45]

Proposed Sections 3, 4 and 5. Current Section 3 (Powers and Duties of Committees) provides that all committees shall have such duties and may exercise such authority as may be prescribed for them in the Exchange Bylaws or in the Rules or by the Board. Current Section 4 (Conduct of Proceedings) provides requirements related to committee proceedings. The Exchange proposes to move current Section 3 to proposed Section 4 and current Section 4 to proposed Section 5.

The Exchange also proposes to adopt proposed Section 3 (General Provisions), which is substantially similar to Article V, Section 5.3 of the NYSE National Bylaws and provides general provisions related to the composition and voting requirements of the committees. Therefore, proposed Section 3 provides as follows:[46]

(a) Except as otherwise provided in this Article IV, each committee shall be comprised of at least three people and may include persons who are not members of the Board; provided, however, that such committee members who are not also members of the Board shall only participate in committee actions to the extent permitted by law. In appointing new members to committees of the Board, the Board is responsible for determining that any such committee meets the composition requirements set forth in this Article IV.

(b) The presence of a majority of the members of a committee shall be necessary to constitute a quorum for the transaction of business at a meeting of a committee.

(c) The act of a majority of the members present at any meeting at which there is a quorum shall be the act of such committee, except as may be otherwise specifically required by these bylaws of the Corporation, the rules, or applicable law.

(d) Unless otherwise restricted by these bylaws, the rules, applicable law, or rules of the particular committee, members of a committee or of any subcommittee thereof may participate in meetings by means of conference call or similar communications equipped by means of which all persons participating in the meeting can hear each other, and such participation shall constitute presence in person at the meeting.

(e) No member of a committee shall participate in the adjudication of any matter in which he or she is personally interested, although his or her presence at a meeting at which such matter is considered shall count toward the quorum requirements for the meeting.

Proposed Section 6. Article 2, Rule 4 (Regulatory Oversight Committee) of the current Rules provides requirements related to size, composition and purpose of the ROC. It states that the ROC ''shall assist the Board in monitoring the design, implementation and effectiveness of the Exchange's programs to promote and enforce compliance with the federal securities laws, SEC rules and CHX rules.'' [47] It provides that the ROC's powers and responsibilities shall be set out in a charter approved by the Board.

The Exchange proposes to delete current Article 2, Rule 4 and add a new Article IV, Section 6 to the proposed Exchange Bylaws. Proposed Section 6 establishes the powers and responsibilities of the ROC, rather than referring to a charter, as in current Article 2, Rule 4. The proposed provision is substantially the same as the related provisions in the governing documents of the other NYSE Group Exchanges,[48] except that the Exchange proposes to add additional language clarifying that the majority affirmative vote requirement is based on the ''directors then in office,'' as opposed to total number of Director slots on the Board. Therefore, proposed Section 6 provides as follows:[49]

(a) The Board shall, on an annual basis, appoint the Regulatory Oversight Committee (''ROC'').

(b) The ROC shall consist of at least three members, each of whom shall be a Public Director of the Corporation. The Board, on affirmative vote of a majority of directors then in office, may, at any time remove a member of the ROC for cause. A failure of the member to qualify as a Public Director shall constitute a basis to remove a member of the ROC for cause. If the term of office of a ROC committee member terminates under this Section, and the remaining term of office of such committee member at the time of termination is not more than three months, during the period of vacancy the relevant committee shall not be deemed to be in violation of the compositional requirements of such ROC by virtue of such vacancy.

(c) The ROC shall oversee the Corporation's regulatory and self-regulatory organization responsibilities and evaluate the adequacy and effectiveness of the Corporation's regulatory and self-regulatory organization responsibilities; assess the Corporation's regulatory performance; and advise and make recommendations to the Board or other committees of the Board about the Corporation's regulatory compliance, effectiveness and plans. In furtherance of its functions, the ROC shall (i) review the regulatory budget of the Corporation and specifically inquire into the adequacy of resources available in the budget for regulatory activities; (ii) meet regularly with the Chief Regulatory Officer in executive session; (iii) in consultation with the Chief Executive Officer of the Corporation, establish the goals, assess the performance, and recommend the compensation of the Chief Regulatory Officer; and (iv) keep the Board informed with respect to the foregoing.

Proposed Section 7. Article 2, Rule 11 (Nominating and Governance Committee) of the current Rules provides that there shall be a Nominating Committee which shall have the composition and responsibilities set out in the Exchange's Bylaws.

The Exchange proposes to delete current Article 2, Rule 11, and add a new Article IV, Section 7 of the proposed Exchange Bylaws. The title of new Section 7 would be ''Nominating Committee,'' and the provision would be substantially similar to Article V, Section 5.7 of the NYSE National Bylaws, except that proposed Section 7 also provides a definition for ''Permit Holder representative.'' Therefore, proposed Section 7 provides that:

The Nominating Committee shall consist solely of Non-Affiliated Directors, as defined above, and/or Permit Holder representatives, and shall be responsible for approving and submitting names of candidates for election to the position of Non-Affiliated Director pursuant to, and in accordance with, Article II, Section 3 and that ''Permit Holder representative'' shall mean an officer, director, employee or agent of a Permit Holder.

Proposed Section 8. Article 2, Rule 2 (Executive Committee) of the current Rules provides requirements related to size, composition and purpose of the Executive Committee.

The Exchange proposes to delete current Article 2, Rule 2 and add a new Article IV, Section 8 of the proposed Exchange Bylaws. The proposed provision provides that the Executive Committee shall consist of Directors, including the Chairman, a majority of the committee members (including the Chairman if the Chairman is a Public Director) shall be Public Directors, the Chairman shall be the Chairman of the Executive Committee and the Executive Committee shall have such powers as may be set forth in the Rules or delegated to it by the Board.

Notably, in an administrative change, proposed Section 8 does not include the provision of the current Article 2, Rule 2 that gives the Executive Committee authority to act for the Board in between

[45] *See* Del. Code tit. 8, § 141(c)(1). The Exchange expects that NYSE National will propose to amend Section 5.2(b) of the NYSE National Bylaws to comport to Article IV, Section 2(b) of the proposed Exchange Bylaws.

[46] *See supra* note 15.

[47] Article 2, Rule 4 of the Rules.

[48] *See* NYSE National Bylaws, Article III, Section 5.6; NYSE Arca Rule 3.3; NYSE Operating Agreement, Article II, Section 2.03(h)(ii); and NYSE American Operating Agreement, Article II, Section 2.03(h)(ii).

[49] *See supra* note 15.

Board meetings, with some limitations.[50] The elimination of such provision would be consistent with the governing documents of the other NYSE Group Exchanges, which, like the proposed provision, allow the relevant board of directors to delegate authority, but do not provide specific committees with the authority to act for the board between meetings.[51]

With respect to proposed Article IV, the Exchange proposes to make conforming amendments to Article 2 of the current Rules, as described below.

Article V (Officers)

Current Article V (Officers) includes provisions related to officers of the Exchange. Generally, the Exchange proposes to amend Article V to be similar to Article VI of the NYSE National Bylaws, as described below. The changes to current Article V are administrative in nature.

Proposed Section 1. Current Section 1 provides that officers of the Exchange shall include the CEO, one or more Vice Presidents, Chief Regulatory Officer, a Secretary, a Treasurer and such other officers as the Board or CEO may determine, and permits the Board or CEO to appoint officers, except that the CEO may only be appointed by the Board.

The Exchange proposes to amend Section 1 to be substantially similar to Article VI, Section 6.1 of the NYSE National Bylaws.[52] Therefore, proposed Section 1 provides that the Board shall elect officers of the Exchange as it deems appropriate, which may include a CEO, President, Chief Regulatory Officer, Secretary, Treasurer, and such other officers as the Board may determine and any two or more offices may be held by the same person, except that the Chief Regulatory Officer and the Secretary may not hold either the office of CEO or President.

Deleting Current Section 2. Current Section 2 (Compensation) provides that the compensation of the CEO shall be fixed by the Compensation Committee and that the compensation of other officers shall be fixed by the CEO in consultation with the Compensation Committee.

As noted above, the Exchange is proposing to eliminate the Compensation Committee, as matters related to compensation of officers will be handled upstream of the Exchange. Such administrative change would be consistent with the other NYSE Group Exchanges, which do not provide for their respective boards of directors to determine officer compensation.[53] Therefore, the Exchange proposes to delete current Section 2 in its entirety.

Proposed Section 2. Current Section 3 (Term of Office; Removal; Vacancies) provides that each officer of the Exchange shall hold office until the officer's successor is appointed and qualified or until the earlier of the officer's death, resignation or removal. It further includes provisions related to the removal of officers.

The Exchange propose to move current Section 3 to proposed Section 2, to amend the provision to be substantially similar to Article VI, Sections 6.2 and 6.3 of the NYSE National Bylaws[54] and to amend the title to state, ''Tenure and Appointment; Removal and Vacancies.'' Specifically, proposed paragraph (a), which is substantially similar to Section Article VI, 6.2 of the NYSE National Bylaws, provides that each officer of the Exchange shall hold office until his or her successor is appointed and qualified, or until his or her earlier death, resignation, retirement or removal. Moreover, proposed paragraph (b), which is substantially similar to Article VI, Section 6.3 of the NYSE National Bylaws, provides that any officer of the Exchange may be removed at any time by the Board, with or without cause, but such removal shall be without prejudice to the contract rights, if any, of the person so removed and that vacancies in any office of the Exchange may be filled for the unexpired term by the Board.

Deleting Current Section 4. Current Section 4 (Chief Executive Officer) includes provisions related to the CEO's obligations, powers and responsibilities. The Exchange notes that none of the other NYSE Group Exchanges have similar provisions in their respective governing documents or rules.[55] The Exchange propose to delete current Section 4 in its entirety.

Deleting Current Section 5. Current Section 5 (Officers Appointed by Chief Executive Officer) includes provisions related to the appointment of officers by the CEO. Given that the CEO will no longer have the authority to appoint officers of the Exchange, pursuant to proposed Section 1, the Exchange propose to delete current Section 5 in its entirety.

Proposed Section 3. The Exchange propose to adopt proposed Section 3 (Powers and Duties), which is similar to Article VI, Section 6.4 of the NYSE National Bylaws and Article V, Section 5.02 of the NYSE Arca Bylaws.[56] Specifically, proposed Section 3 provides that each of the offices of the Exchange shall, unless otherwise ordered by the Board, have such powers and duties as customarily pertain to the respective office, and such further powers and duties as from time to time may be conferred by the Board, or by an officer delegated such authority by the Board.

Article VI (Indemnification)

Current Article VI includes various provisions related to indemnification by the Exchange.

Given that the Exchange is now a wholly-owned indirect subsidiary of ICE, the Exchange believes it appropriate to harmonize the Exchange's indemnification provisions with those of ICE and the Exchange's intermediate holding company, ICE Holdings.[57]

Specifically, the Exchange proposes to delete Sections 1–5 under current Article VI in their entirety and replace it with proposed Section 1 (Indemnification), which is substantially similar to the ICE and ICE Holdings provisions, except that proposed Section 1 utilizes the term ''officer'' instead of ''Senior Officers,'' so as to be consistent with the Exchange's

[50] Article 2, Rule 2 of the CHX Rules provides that ''between meetings of the Board of Directors, [the Executive Committee] shall have, and may exercise, all the rights, powers, authority, duties and obligations of the Board of Directors not otherwise delegated to another committee or an officer or officers of the Exchange by the bylaws, rules or by the Board of Directors, except the authority to propose amendments to the certificate of incorporation, to adopt an agreement of merger or consolidation, to recommend to stockholders the sale, lease or exchange of all or substantially all of the property and assets of the Exchange or to recommend to the stockholders a dissolution of the Exchange or the revocation of a dissolution.''

[51] *See* NYSE Arca Bylaws Article IV, Section 4.01(a); NYSE National Bylaws Article V, Section 5.1; NYSE Operating Agreement, Article II, Section 2.03(h); and NYSE American Operating Agreement, Article II, Section 2.03(h).

[52] *See also* NYSE Arca Bylaws, Article V, Section 5.01.

[53] *See* NYSE National Bylaws, Article IV; NYSE Arca Bylaws, Article V; NYSE Operating Agreement, Article II, Section 2.04; and NYSE American Operating Agreement, Article II, Section 2.04.

[54] The proposed provision is consistent with the governing documents of the other NYSE Group Exchanges. *See* NYSE Arca Bylaws, Article V, Section 5.03; NYSE Operating Agreement, Article II, Section 2.04(b); and NYSE American Operating Agreement, Article II, Section 2.04(b).

[55] *See* NYSE National Bylaws, Article IV; NYSE Arca Bylaws, Article V; NYSE Operating Agreement, Article II, Section 2.04; and NYSE American Operating Agreement, Article II, Section 2.04.

[56] The proposed provision is consistent with the governing documents of the other NYSE Group Exchanges. *See* NYSE Operating Agreement, Article II, Section 2.04(c); and NYSE American Operating Agreement, Article II, Section 2.04(c).

[57] *See* ICE Bylaws, Article X, Section 10.6, and ICE Holdings Bylaws, Article X, Section 10.6.

terminology. Therefore, proposed Section 1 provides as follows: [58]

(a) The Exchange shall, to the fullest extent permitted by law, as those laws may be amended and supplemented from time to time, indemnify any director or officer made, or threatened to be made, a party to any action, suit or proceeding, whether criminal, civil, administrative or investigative, by reason of being a director or officer of the Exchange or a predecessor corporation or, at the Exchange's request, a director, officer, partner, member, employee or agent of another corporation or other entity; provided, however, that the Exchange shall indemnify any director or officer in connection with a proceeding initiated by such person only if such proceeding was authorized in advance by the Board of Directors of the Exchange. The indemnification provided for in this Section 7.6 shall:

(i) Not be deemed exclusive of any other rights to which those indemnified may be entitled under any bylaw, agreement or vote of stockholders or disinterested directors or otherwise, both as to action in their official capacities and as to action in another capacity while holding such office; (ii) continue as to a person who has ceased to be a director or officer; and (iii) inure to the benefit of the heirs, executors and administrators of an indemnified person.

(b) Expenses incurred by any such person in defending a civil or criminal action, suit or proceeding by reason of the fact that he is or was a director or officer of the Exchange (or was serving at the Exchange's request as a director, officer, partner, member, employee or agent of another corporation or other entity) shall be paid by the Exchange in advance of the final disposition of such action, suit or proceeding upon receipt of an undertaking by or on behalf of such director or officer to repay such amount if it shall ultimately be determined that he or she is not entitled to be indemnified by the Exchange as authorized by law. Notwithstanding the foregoing, the Exchange shall not be required to advance such expenses to a person who is a party to an action, suit or proceeding brought by the Exchange and approved by a majority of the Board of Directors of the Exchange that alleges willful misappropriation of corporate assets by such person, disclosure of confidential information in violation of such person's fiduciary or contractual obligations to the Exchange or any other willful and deliberate breach in bad faith of such person's duty to the Exchange or its stockholders.

(c) The foregoing provisions of this Section 7.6 shall be deemed to be a contract between the Exchange and each director or officer who serves in such capacity at any time while this bylaw is in effect, and any repeal or modification thereof shall not affect any rights or obligations then existing with respect to any state of facts then or theretofore existing or any action, suit or proceeding theretofore or thereafter brought based in whole or in part upon any such state of facts. The rights provided to any person by this bylaw shall be enforceable against the Exchange by such person, who shall be presumed to have relied upon it in serving or continuing to serve as a director or officer or in such other capacity as provided above.

(d) The Board of Directors in its discretion shall have power on behalf of the Exchange to indemnify any person, other than a director or officer, made or threatened to be made a party to any action, suit or proceeding, whether criminal, civil, administrative or investigative, by reason of the fact that such person, or his or her testator or intestate, is or was an officer, employee or agent of the Exchange or, at the Exchange's request, is or was serving as a director, officer, partner, member, employee or agent of another corporation or other entity.

(e) To assure indemnification under this Section 7.6 of all directors, officers, employees and agents who are determined by the Exchange or otherwise to be or to have been ''fiduciaries'' of any employee benefit plan of the Exchange that may exist from time to time, Section 145 of the Delaware General Corporation Law shall, for the purposes of this Section 7.6, be interpreted as follows: An ''other enterprise'' shall be deemed to include such an employee benefit plan, including without limitation, any plan of the Exchange that is governed by the Act of Congress entitled ''Employee Retirement Income Security Act of 1974,'' as amended from time to time; the Exchange shall be deemed to have requested a person to serve an employee benefit plan where the performance by such person of his duties to the Exchange also imposes duties on, or otherwise involves services by, such person to the plan or participants or beneficiaries of the plan; excise taxes assessed on a person with respect to an employee benefit plan pursuant to such Act of Congress shall be deemed ''fines.''

Deleting Sections 2–5. The Exchange notes that current Section 2 (Contract) is a statement of law regarding the enforceability of contracts, and therefore is in effect regardless of whether the provision is included in the Exchange Bylaws. Therefore, the Exchange proposes to delete current Section 2 in its entirety.

The Exchange proposes to delete current Section 3 (Discretionary Indemnification Coverage) and Section 4 (Continuity of Indemnification), as discretionary indemnification by the Board is addressed in proposed Section 1(d) and continuity of indemnification is addressed in proposed Section 1(a).

Finally, the Exchange proposes to delete Section 5 (Corporation Not Liable). A more comprehensive statement of the Exchange's limitation of liability may be found under Article 3, Rule 19 of the Rules. The Exchange proposes to delete Section 5 as duplicative of such Rule 19. The Exchange believes that having Article 2, Rule 19 of the Rules be the sole statement of the Exchange's limitation of liability provisions will reduce possible confusion that may result from a restatement of such provisions under the Exchange Bylaws and is also consistent with the Exchange's observation that Participants are more likely to utilize the Rules as a reference to the operation and obligations of the Exchange rather than the Exchange Bylaws.

Article VII (Amendments)

Proposed Section 1. Current Section 1 (Bylaws) provides that the Exchange Bylaws may be modified by the Board or the stockholders.

The Exchange proposes to amend Section 1 (Bylaws) to be similar to Article VIII, Section 8.1 of the NYSE National Bylaws. Specifically, proposed Section 1 maintains the language from current Section 1 with an additional sentence stating that before any amendment to, alteration or repeal of any provision of the bylaws of the Exchange under this Article VII shall be effective, those changes shall be submitted to the Board and if the same must be filed with or filed with and approved by the Commission, then the proposed changes to the bylaws of the Exchange shall not become effective until filed with or filed with and approved by the Commission, as the case may be.

The Exchange does not propose to adopt the contractual provision in Section 8.1 of the NYSE National Bylaws that requires shareholder action to effect amendments to certain of the bylaws. The current Exchange Bylaws does not have a similar requirement, and the Exchange notes the bylaws of other national securities exchanges, such as Cboe BZX, similarly permit amendments to the bylaws be effected by either the board or shareholders, without carving out exceptions.[59]

Article VIII (Certificates of Stock and Their Transfer)

Article VIII contains provisions relating to the certificates of stock of the Exchange. Except as set forth below, the Exchange proposes to conform the provisions in Article VIII to Article IX of the NYSE National Bylaws, so as streamline provisions across the two NYSE Group Exchanges that have stock certificates, for the sake of efficiency. The proposed changes are administrative in nature, relating primarily to the administrative processes relating to shares, and will

[58] *See supra* note 15.

[59] *See* CBOE Exchange Bylaws, Article IX, Sections 9.1 and 9.2; Cboe BZX Bylaws, Article IX, Sections 9.1 and 9.2; *see also* NYSE Arca Bylaws Article IX (providing that the bylaws may be amended by the NYSE Arca board of directors, without requiring action by the member).

have no material substantive effect on the current operations or governance of the Exchange.

Proposed Section 1. Current Section 1 (Form and Execution of Certificates) provides requirements related to the execution of stockholder certificates.

The Exchange proposes to amend Section 1 to be largely similar to Article IX, Section 9.1 of the NYSE National Bylaws. Specifically, proposed Section 1 maintains the substance of current Section 1, but includes additional language that any and all signatures on a certificate may be facsimiles. However, proposed Section 1 differs from Article IX, Section 9.1 of the NYSE National Bylaws in that proposed Section 1 provides that the certificate may be signed by ''any two authorized officers,'' instead of listing the specific officers authorized to execute a certificate, which better reflects the requirements of Section 158 of the DGCL.[60]

Proposed Section 2. Current Section 2 (Conditions to Transfer) sets forth the documentation required for a sale, transfer or other disposition of stock of the Exchange.

The Exchange proposes to amend Section 2 to be substantially similar to Article IX, Section 9.4 of the NYSE National Bylaws. Specifically, proposed Section 2 adopts taxonomy similar to Article IX, Section 9.4 of the NYSE National Bylaws, and omits current clause (d), which permits the CEO to adopt additional procedures with respect to the transfer of stock. The change is administrative.

Proposed Section 3. Current Section 3 (Replacement Certificates) provides the Board with the authority to direct that new stockholder certificates be issued.

The Exchange proposes to amend Section 3 to be substantially similar to Article IX, Section 9.2 of the NYSE National Bylaws. Notably, consistent with the DGCL,[61] proposed Section 3 states that the Exchange generally (as opposed to the Board specifically) has the authority to issue replacement certificates, clarifies that the Exchange can issue one or more replacement certificates and replaces the pronoun ''his'' with the more specific ''such owner's.''

Proposed Section 6. The Exchange propose to adopt Section 6 (Notice on Certificates), which is substantially similar to Article IX, Section 9.3 of the NYSE National Bylaws and consistent with the DGCL[62] for shares subject to certain restrictions and limitations.

Article IX (Self-Regulatory Function of the Corporation)

Current Article IX (Contracts, Loans, Checks and Deposits) includes administrative provisions related to authority to execute contracts (Section 1) and loans (Section 2); issue checks or other negotiable instruments (Section 3); and deposit of Exchange funds (Section 4). Section 1 is a statement of law regarding the persons authorized to execute contracts on behalf of the Exchange. Also, the Exchange notes that none of the other NYSE Group Exchanges have provisions similar to Sections 2–4 in their respective governing documents or rules. Therefore, the Exchange proposes to delete current Article IX in its entirety. As the provisions are administrative, the proposed deletion would have no material substantive effect on the current operations or governance of the Exchange.

Current Article X (Self-Regulatory Function of the Corporation) includes special obligations and requirements related to the Exchange's status as an SRO. The Exchange proposes to move current Article X to proposed Article IX and to amend certain provisions to be similar to related provisions under Article X of the NYSE National Bylaws, as follows.

Proposed Section 1. Current Section 1 (Management of the Corporation) requires the Board to consider the Exchange's SRO status and certain requirements under the Exchange Act when managing the business and affairs of the Exchange.

Proposed Section 1 maintains the substance of current Section 1, but includes various non-substantive terminology changes, including replacing a reference to ''Exchange Act of 1934'' with ''Exchange Act,'' which is a defined term under the Exchange Bylaws.[63]

Proposed Section 2. Current Section 2 (Participation in Board and Committee Meetings) prohibits any persons that are not Directors or necessary officers, staff, counsel or other advisors from participating in Board and committee meetings.

Proposed Section 2 maintains the substance of current Section 2, but includes various non-substantive terminology changes, including replacing a reference to ''committees of the Corporation'' with ''committees of the Board,'' which is consistent with language used under Article II of the proposed Exchange Bylaws.

Proposed Section 3. Current Section 3 (Confidentiality of Information and Records Relating to SRO Function) requires certain books and records of the Exchange to remain confidential with certain specified exceptions.

The Exchange proposes to amend Section 3 to be substantially similar to Article X, Section 10.3 of the NYSE National Bylaws. Proposed Section 3 maintains the substance of current Section 3 and includes additional language (a) permitting disclosure of the specified confidential information to ''personnel of the Commission'' and (b) stating that nothing in such Section shall be interpreted as to limit or impede the rights of the Commission to access and examine confidential information pursuant to the federal securities laws and the rules and regulations thereunder, or to limit or impede the ability of any officers, directors, employees or agents of the Corporation to disclose such confidential information to the Commission.

Proposed Section 5. Current Section 5 (Regulatory Fees and Penalties) requires that any revenues received by the Exchange from regulatory fees or regulatory penalties be applied to fund the legal and regulatory operations of the Exchange only.

The Exchange proposes to maintain the substance of Section 5, but to substantially conform the provision to the governing documents of the other NYSE Group Exchanges.[64] The proposed language would expand the scope of the provision to include regulatory assets and fines as well as fees or penalties, and would add a prohibition on the payment of distributions to other entities. Therefore, proposed Section 5 provides as follows: [65]

> Any regulatory assets or any regulatory fees, fines or penalties collected by the Exchange's regulatory staff will be applied to fund the legal, and regulatory and surveillance operations of the Exchange, and the Exchange shall not distribute such assets, fees fines or penalties to pay dividends or be distributed to any other entity. For purposes of this Section, regulatory penalties shall include restitution and disgorgement of funds intended for customers.

Article X (General Provisions)

Current Article XI (General Provisions) includes provisions related to the Exchange's fiscal year (Section 1),

[60] *See* Del. Code tit. 8, § 158.

[61] *See* Del. Code tit. 8, § 167.

[62] *See* Del. Code tit. 8, § 202.

[63] *See* Article II, Section 2 of the proposed Exchange Bylaws.

[64] *See* NYSE National Bylaws, Article X, Section 10.4; NYSE Arca Bylaws, Article II, Section 2.06; NYSE Operating Agreement, Article IV, Section 4.05; and NYSE American Operating Agreement, Article IV, Section 4.05.

[65] *See supra* note 15.

the payment of dividends (Section 2), reserve funds (Section 3), subsidiary corporations (Section 4) and severability (Section 5). The Exchange proposes to move current Article XI to proposed Article X and to amend certain sections thereunder as follows.

Proposed Section 2. Current Section 2 (Dividends) permits the Board to declare dividends upon the capital stock of the Exchange.

Proposed Section 2 maintains the substance of current Section 2, except that it replaces the phrase ''Subject to any provisions or any applicable statute,'' which qualifies the Board's authority to issue dividends, with ''Subject to any applicable law'' so as to eliminate redundant language and clarify that proposed Section 2 would be subject to any non-statutory law, such as common law.

Proposed Section 4. Current Section 4 (Subsidiary Corporations) authorizes the Board to constitute any officer of the Exchange to vote the stock of any subsidiary corporation on behalf of the Exchange and, in absence of specific action by the Board, the CEO has the authority to represent the Corporation and to vote the stock of any subsidiary corporation on behalf of the Exchange.

Proposed Section 4 maintains the substance of current Section 4, except that it authorizes the CEO and the ''Secretary of the Corporation'' to act on behalf of the Exchange pursuant to proposed Section 4. The Exchange believes that permitting the Secretary of the Exchange to act on behalf of the Exchange pursuant to proposed Section 4 is appropriate given that the Secretary is frequently tasked to execute the Exchange's actions, especially as it relates to corporate governance.

The change is administrative and non-controversial. Under Section 4, the Board may constitute any officer of the Exchange, which includes the Secretary, to vote the stock of any subsidiary of the Exchange. The Board has approved the proposed changes to the Bylaws, including the proposed changes to Section 4 adding the reference to the Secretary of the Exchange. By approving the proposed changes to Section 4, the Board granted the Secretary the authority described therein. Moreover, proposed Section 4 would continue to permit the Board to revoke such voting power or constitute another officer with such voting power.

c. Holdings Bylaws

Article VII, Section 7.6 (Indemnification and Insurance)

Section 7.6 of the current Holdings Bylaws contains various provisions related to indemnification and insurance. To better align the indemnification provisions of the Holdings Bylaws with those of ICE, ICE Holdings, and the proposed Exchange Bylaws, the Exchange proposes to replace current subparagraphs (A) through (K) with proposed subparagraphs (A) through (E), which are identical to paragraphs (a)–(e) of Article VI of the proposed Exchange Bylaws.

Article XII, Section 12.1 (Waiver of Ownership Limits and Voting Limits To Permit Merger)

Article XII, Section 12.1 of the Holdings Bylaws was adopted prior to the acquisition of the Exchange and Holdings by ICE, and made certain determinations with respect to ICE, ICE Holdings, NYSE Holdings and NYSE Group and the acquisition that were necessary for the waiver of ownership and voting limitations then in place.[66] As the acquisition is complete, the provision is obsolete. Accordingly, the Exchange proposes to delete it.

Article VIII Through Article XI

Each of Articles VIII through XI of the Holdings Bylaws are currently marked as ''Reserved.'' In light of the proposed deletion of Article XII of the Holdings Bylaws, as described above, the Exchange proposes to delete Articles VIII through XI as no longer necessary.

d. Rules

In light of the Article IV of the proposed Exchange Bylaws, the Exchange proposes to amend Article 2 of the current Rules to effect the following changes:

- Amend Rule 1 (Appointment and Approval) to provide that the committees provided for in this Article shall be appointed as provided in the Exchange Bylaws or as set out in Article 2 of the proposed Rules, and to eliminate language related to the appointment of members of committees of the Board, as Article IV of the proposed Exchange Bylaws supersedes such provisions.
- Delete current Rules 2 (Executive Committee), 3 (Finance Committee) and 4 (Regulatory Oversight Committee), as the provisions related to the Executive Committee are now under Article IV, Section 8 of the proposed Exchange Bylaws; the Finance Committee has been eliminated, as noted above; and the provisions related to the ROC are now under Article IV, Section 6 of the proposed Exchange Bylaws.
- Move current Rule 5 (Committee on Exchange Procedure) to proposed Rule 2 and eliminate reference to current Rule 10, as it will no longer exist, as noted below. Correspondingly, amend Article 20, Rule 10(e)(2)(A) to replace reference to ''Article 2, Rule 5'' with ''Article 2, Rule 2.''
- Delete current Rule 6 (Reserved), as it is currently a placeholder citation.
- Move current Rule 7 (Judiciary Committee) to proposed Rule 3.
- Delete current Rules 8 (Compensation Committee) and 9 (Audit Committee), as the Compensation and Audit Committees have been eliminated, as noted above. Correspondingly, the Exchange proposes to replace references to the ''Audit Committee of the Board'' under Article 22, Rule 19(m)(5)(B) of the current Rules with ''Board.''
- Delete current Rule 10 (Participant Advisory Committee) as none of the other NYSE Group Exchanges have a similar committee. The Exchange believes that the requirement that the Board be composed of at least 20% Non-Affiliated Directors[67] and that the Committee on Exchange Procedure[68] and the Judiciary Committee[69] be comprised solely of Participants ensure fair representation of Participants on the Board.
- Delete current Rule 11 (Nominating and Governance Committee) as it has been restated under Article IV, Section 7 of the proposed Exchange Bylaws.
- Move current Rule 12 (Committee Quorum) to proposed Rule 4 and eliminate language related to quorums of committees of the Board, as committee quorum is now addressed under Article IV, Section 3(b) of the proposed Exchange Bylaws. Therefore, proposed Rule 4 provides that one-half of its members, including the ex-officio ones, shall constitute a quorum of each committee provided for in Article 2 of the proposed Rules, which only includes the Committee on Exchange Procedure and the Judiciary Committee, neither of which are committees of the Board.

In addition, the Exchange proposes to correct a typographical error under the first sentence of Article 18, Rule 1(b)(5) to delete the words ''the of.''

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Exchange Act,[70] in

[66] *See* 83 FR 34182, *supra* note 5, at 34184.

[67] *See* Article II, Section 2 of the proposed Exchange Bylaws.

[68] *See* Article 2, Rule 2 of the proposed Rules.

[69] *See* Article 2, Rule 3 of the proposed Rules.

[70] 15 U.S.C. 78f(b).

general, and furthers the objectives of Section 6(b)(1)[71] in particular, in that it enables the Exchange to be so organized as to have the capacity to be able to carry out the purposes of the Exchange Act and to comply, and to enforce compliance by its exchange members and persons associated with its exchange members, with the provisions of the Exchange Act, the rules and regulations thereunder, and the rules of the Exchange.

Specifically, the proposed amendments related to the name change of the Exchange and Holdings are non-substantive changes that do not impact the governance or ownership of the Exchange. The Exchange believes that the proposed amendments would enable the Exchange to continue to be so organized as to have the capacity to carry out the purposes of the Exchange Act and comply and enforce compliance with the provisions of the Exchange Act by its members and persons associated with its members, because ensuring that the Exchange Certificate and Bylaws, Holdings Certificate and Bylaws, Rules and Fee Schedule accurately reflect the name changes would contribute to the orderly operation of the Exchange by adding clarity and transparency to such documents and rules.

The Exchange believes that the proposed amendments to the Exchange Bylaws and Certificate would enable the Exchange to be so organized as to have the capacity to be able to carry out the purposes of the Exchange Act and to comply, and to enforce compliance by its exchange members and persons associated with its exchange members, with the provisions of the Exchange Act, the rules and regulations thereunder, and the rules of the Exchange, because such amendments would add or expand upon existing provisions to protect and maintain the independence and integrity of the Exchange and its regulatory function and reinforce the notion that the Exchange is not solely a commercial enterprise, but a national securities exchange subject to the obligations imposed by the Exchange Act. Such provisions include vesting the Board with all powers necessary for the governing of the Exchange as an ''exchange'' within the meaning of the Exchange Act and the regulation of the business conduct of any Participant; ensuring that regulatory assets, fees, fines, and penalties may only be used to fund legal, regulatory and surveillance operations; and providing that any amendments to the Exchange Bylaws or Certificate must be submitted to the Board and, as applicable, shall not be effective until filed with or filed with and approved by the Commission. The Exchange believes that such provisions are consistent with and will facilitate a governance structure that will provide the Commission with appropriate oversight tools to ensure that the Commission will have the ability to enforce the Exchange Act with respect to the Exchange.

The Exchange believes that the provisions relating to Board committees contemplated by the proposed rule change would enable the Exchange to be so organized as to have the capacity to be able to carry out the purposes of the Exchange Act and to comply, and to enforce compliance by its exchange members and persons associated with its exchange members, with the provisions of the Exchange Act, the rules and regulations thereunder, and the rules of the Exchange, because they would incorporate the establishment and responsibilities of each Board committee, as well as more general provisions regarding their composition, quorum and voting requirements, into the Exchange governing documents. In particular, the Exchange believes that, by establishing the powers and responsibilities of the ROC, proposed Article IV, Section 6 of the Exchange Bylaws, is designed to insulate the Exchange's regulatory functions from its market and other commercial interests so that the Exchange can carry out its regulatory obligations in furtherance of Section 6(b)(1) of the Exchange Act. Indeed, the Exchange believes that inclusion of the provision in the Exchange Bylaws would underscore the importance of the Exchange's regulatory function and specifically empower an independent committee of the Board to oversee regulation and meet regularly with the Chief Regulatory Officer.

At the same time, the Exchange believes that the proposal to eliminate the requirement that the Exchange maintain Audit, Compensation and Finance Committees is consistent with Section 6(b)(1) of the Exchange Act because audit, compensation and financial matters would be addressed by the Board or by the audit and compensation committees of ICE, as applicable. The proposed change would streamline corporate governance and enhance efficiency and consistency by ensuring that such matters are addressed in the same manner among the NYSE Group Exchanges.

Also, the proposed amendments to harmonize certain provisions under the Exchange Certificate and Bylaws with similar provisions under the governing documents of other NYSE Group Exchanges, ICE and ICE Holdings would contribute to the orderly operation of the Exchange and would enable the Exchange to be so organized as to have the capacity to carry out the purposes of the Exchange Act and comply with the provisions of the Exchange Act by its members and persons associated with members. For example, the proposed changes would create greater conformity between the Exchange's provisions relating to stockholders, officers, and stock certificates and those of its affiliates, particularly NYSE National and NYSE Arca. The Exchange believes that such conformity would streamline the NYSE Group Exchanges' corporate processes, create more equivalent governance processes among them, and also provide clarity to the Exchange's members, which is beneficial to both investors and the public interest. At the same time, the Exchange will continue to operate as a separate self-regulatory organization and to have rules, membership rosters and listings distinct from the rules, membership rosters and listings of the other NYSE Group Exchanges.

Finally, the proposed amendments to clarify the meaning of certain provisions under the Exchange Certificate and the Exchange Bylaws, to better comport certain provisions with the DGCL and to effect non-substantive changes would facilitate the Exchange's continued compliance with the Exchange Certificate and Bylaws and applicable law, which would further enable the Exchange to be so organized as to have the capacity to be able to carry out the purposes of the Exchange Act and to comply, and to enforce compliance by its exchange members and persons associated with its exchange members, with the provisions of the Exchange Act, the rules and regulations thereunder, and the rules of the Exchange.

For these reasons, the Exchange believes that the proposed rule change is consistent with Section 6(b)(1) of the Exchange Act.[72]

The Exchange also believes that the proposed rule change is consistent with Section 6(b)(5) of the Exchange Act,[73] in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

[71] 15 U.S.C. 78f(b)(1).

[72] 15 U.S.C. 78f(b)(1).

[73] 15 U.S.C. 78f(b)(5).

Specifically, the proposed amendments related to the name changes would reduce potential investor and market participant confusion and therefore remove impediments to and perfect the mechanism of a free and open market and a national market system by ensuring that investors and market participants can more easily navigate, understand and comply with the Exchange Certificate and Bylaws, Holdings Certificate and Bylaws, Rules and Fee Schedule.

Also, the proposed amendments to harmonize certain provisions under the Exchange Certificate and Bylaws with similar provisions under the governing documents of certain Exchange affiliates would promote consistency among the governing documents of the NYSE Group Exchanges, ICE and ICE Holdings, which would promote the maintenance of a fair and orderly market, the protection of investors and the protection of the public interest. The proposed amendments would make the governing framework, corporate requirements and administrative processes relating to the Board, Board committees, officers, stockholders, and other corporate matters more similar to those of the NYSE Group Exchanges, in particular NYSE National and NYSE Arca, which have been well-established as fair and designed to protect investors and the public interest.[74]

In particular, the Exchange believes that, by establishing the powers and responsibilities of the ROC; vesting the Board with all powers necessary for the governing of the Exchange as an ''exchange'' within the meaning of the Exchange Act and the regulation of the business conduct of any Participant; ensuring that regulatory assets, fees, fines, and penalties may only be used to fund legal, regulatory and surveillance operations; and providing that any amendments to the Exchange Bylaws or Certificate must be submitted to the Board and, as applicable, shall not be effective until filed with or filed with and approved by the Commission, the proposed rule change would act to insulate the Exchange's regulatory functions from its market and other commercial interests so that the Exchange can carry out its regulatory obligations, ensuring that Participants are protected from unfair, unfettered actions by an exchange pursuant to its rules, and that, in general, the Exchange is administered in a way that is equitable to all those who trade on its market or through its facilities. Therefore, the Exchange believes that the proposed rule change would prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, foster cooperation and coordination with persons engaged in facilitating transactions in securities, remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, protect investors and the public interest.

Finally, the proposed amendments to clarify the meaning of certain provisions under the Exchange Certificate and the Exchange Bylaws, to better comport certain provisions with the DGCL and effect non-substantive changes removes impediments to and perfects the mechanism of a free and open market by removing confusion that may result from corporate governance provisions that are either unclear or inconsistent with the governing law. The Exchange also believes that the proposed amendments remove impediments to and perfects the mechanism of a free and open market by ensuring that persons subject to the Exchange's jurisdiction, regulators, and the investing public can more easily navigate and understand the governing documents. The Exchange further believes that the proposed amendments would not be inconsistent with the public interest and the protection of investors because investors will not be harmed and in fact would benefit from increased transparency and clarity, thereby reducing potential confusion.

For these reasons, the Exchange believes that the proposed rule change is consistent with and facilitates a governance and regulatory structure that furthers the objectives of Section 6(b)(5) of the Exchange 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 purposes of the Exchange Act. The proposed rule change is not intended to address competitive issues but rather is concerned solely with the marketing and corporate governance and administration of the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[75] and Rule 19b–4(f)(6) thereunder.[76]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–CHX–2018–05 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CHX–2018–05. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the

[74] *See* 83 FR 24517, 25431, *supra* note 5.

[75] 15 U.S.C. 78s(b)(3)(A).

[76] 17 CFR 240.19b–4(f)(6). As required under Rule 19b–4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.

Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CHX–2018–05, and should be submitted on or before November 23, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[77]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–23844 Filed 10–31–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 33283]

Notice of Applications for Deregistration Under Section 8(f) of the Investment Company Act of 1940

October 26, 2018.

The following is a notice of applications for deregistration under section 8(f) of the Investment Company Act of 1940 for the month of October 2018. A copy of each application may be obtained via the Commission's website by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090. An order granting each application will be issued unless the SEC orders a hearing. Interested persons may request a hearing on any application by writing to the SEC's Secretary at the address below and serving the relevant applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on November 20, 2018, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to Rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: The Commission: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

FOR FURTHER INFORMATION CONTACT: Shawn Davis, Branch Chief, at (202) 551–6413 or Chief Counsel's Office at (202) 551–6821; SEC, Division of Investment Management, Chief Counsel's Office, 100 F Street NE, Washington, DC 20549–8010.

Advent Claymore Convertible Securities and Income Fund II [File No. 811–22022]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to Advent Claymore Convertible Securities and Income Fund and, on August 27, 2018, made a final distribution to its shareholders based on net asset value. Expenses of $578,871 incurred in connection with the reorganization were paid by the applicant.

Filing Dates: The application was filed on August 29, 2018, and amended on August 30, 2018 and October 12, 2018.

Applicant's Address: 888 Seventh Avenue, 31st Floor, New York, New York 10019.

Advent/Claymore Enhanced Growth & Income Fund [File No. 811–21504]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to Advent Claymore Convertible Securities and Income Fund and, on August 27, 2018, made a final distribution to its shareholders based on net asset value. Expenses of $260,023 incurred in connection with the reorganization were paid by applicant.

Filing Dates: The application was filed on August 29, 2018, and amended on October 12, 2018.

Applicant's Address: 888 Seventh Avenue, 31st Floor, New York, New York 10019.

First Trust Strategic High Income Fund II [File No. 811–21842]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to First Trust High Income Long/Short Fund and, on June 25, 2018, made a final distribution to its shareholders based on net asset value. Expenses of $452,574 incurred in connection with the reorganization were paid by the applicant and the applicant's investment adviser.

Filing Dates: The application was filed on August 16, 2018, and amended on October 9, 2018.

Applicant's Address: 120 East Liberty Drive, Suite 400, Wheaton, Illinois 60187.

Kayne Anderson Energy Development Company [File No. 811–22435]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to Kayne Anderson MLP/Midstream Investment Company and, on August 6, 2018, made a final distribution to its shareholders based on net asset value. Expenses of approximately $874,000 incurred in connection with the reorganization were paid by the applicant and the acquiring fund.

Filing Dates: The application was filed on August 20, 2018, and amended on October 9, 2018.

Applicant's Address: 811 Main Street, 14th Floor, Houston, Texas 77002.

Kayne Anderson Energy Total Return Fund, Inc. [File No. 811–21750]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to Kayne Anderson Midstream/Energy Fund, Inc., and, on August 6, 2018, made a final distribution to its shareholders based on net asset value. Expenses of approximately $884,000 incurred in connection with the reorganization were paid by the applicant and the acquiring fund.

Filing Dates: The application was filed on August 20, 2018, and amended on October 9, 2018.

Applicant's Address: 811 Main Street, 14th Floor, Houston, Texas 77002.

Managed High Yield Plus Fund Inc. [File No. 811–08765]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On June 29, 2016

[77] 17 CFR 200.30–3(a)(12).

and June 29, 2018, applicant made liquidating distributions to its shareholders based on net asset value. Expenses of $98,189 incurred in connection with the liquidation were paid by the applicant.

Filing Date: The application was filed on September 14, 2018.

Applicant's Address: c/o UBS Asset Management (Americas) Inc., Attn: Keith A. Weller, 1285 Avenue of the Americas, 12th Floor, New York, New York 10019–6028.

Nuveen Active Allocation Real Return Fund [File No. 811–22688]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicant has never made a public offering of its securities and does not propose to make a public offering or engage in business of any kind.

Filing Date: The application was filed on August 23, 2018.

Applicant's Address: 333 West Wacker Drive, Chicago, Illinois 60606.

Strategic Global Income Fund, Inc. [File No. 811–06475]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On June 29, 2016 and July 11, 2018, applicant made liquidating distributions to its shareholders based on net asset value. Expenses of $68,830 incurred in connection with the liquidation were paid by the applicant.

Filing Date: The application was filed on September 14, 2018.

Applicant's Address: c/o UBS Asset Management (Americas) Inc., Attn: Keith A. Weller, 1285 Avenue of the Americas, 12th Floor, New York, New York 10019–6028.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–23849 Filed 10–31–18; 8:45 am]

BILLING CODE P

SOCIAL SECURITY ADMINISTRATION

[Docket No. SSA–2018–0059]

Privacy Act of 1974; System of Records

AGENCY: Social Security Administration (SSA).

ACTION: Notice of a modified system of records.

SUMMARY: In accordance with the Privacy Act, we are issuing public notice of our intent to modify our existing systems of records listed below under the System Name and Number section. This notice publishes details of the modification as set forth under the caption, **SUPPLEMENTARY INFORMATION**.

DATES: This routine use is effective December 3, 2018. We invite public comment on the addition of this routine use. In accordance with 5 U.S.C. 552a(e)(4) and (e)(11), the public is given a 30-day period in which to submit comments. Therefore, please submit any comments by December 3, 2018.

ADDRESSES: The public, OMB, and Congress may comment on this publication by writing to the Executive Director, Office of Privacy and Disclosure, Office of the General Counsel, SSA, Room G–401 West High Rise, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, or through the Federal e-Rulemaking Portal at *http://www.regulations.gov;* please reference docket number SSA–2018–0059. All comments we receive will be available for public inspection at the above address and we will post them to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Elizabeth Boorstein, Government Information Specialist, Privacy Implementation Division, Office of Privacy and Disclosure, Office of the General Counsel, SSA, Room G–401 West High Rise, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, telephone: (410) 966–2824, email: *Elizabeth.Boorstein@ssa.gov.*

SUPPLEMENTARY INFORMATION: The Office of Management and Budget (OMB) Memorandum 17–12 (M–17–12), Preparing for and Responding to a Breach of Personally Identifiable Information (January 3, 2017) requires Federal agencies to publish a routine use in its systems of records that authorizes disclosure of records that may reasonably be needed by a Federal agency or Federal entity in connection with the response and remedial efforts in the event of a breach. The proposed routine use permits SSA to disclose records that may reasonably be needed by another Federal agency or Federal entity in its efforts to respond and remediate a breach of personally identifiable information. Such a routine use will serve to protect the interests of the people whose information is at risk by allowing SSA to assist another Federal agency or Federal entity to take appropriate steps to facilitate a timely and effective response to a confirmed or suspected breach. It will also help SSA improve its ability to prevent, minimize, or remedy any harm that may result from a compromise of data maintained in SSA's systems of records. Such a use is in the best interest of both the individual whose record is at issue and the public.

To satisfy the routine use requirements in OMB M–17–12, SSA is adding the following routine use to our Privacy Act systems of records: [1]

To another Federal agency or Federal entity, when SSA determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in:

(a) responding to a suspected or confirmed breach; or

(b) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

SYSTEM NAME AND NUMBER

SSA will establish the new routine use listed above in the following systems of records:

[1] Privacy Act systems of records that contain data protected under the Internal Revenue Code (IRC) will not contain this routine use as the IRC does not contain a provision that permits disclosure for this purpose.

System No. and name	New routine use	**Federal Register** citation No./ publication date
60–0003—Attorney Fee File	No. 10	71 FR 1803, 01/11/06. 72 FR 69723, 12/10/07.
60–0004—Working File of the Appeals Council	No. 8	74 FR 19620, 04/29/09.
60–0005—Administrative Law Judge Working File on Claimant Cases	No. 9	70 FR 60383, 10/17/09.
60–0006—Storage of Hearing Records: Tape Cassettes and Audiograph Discs	No. 9	71 FR 1805, 01/11/06. 72 FR 69723, 12/10/07.
60–0009—Hearings and Appeals Case Control System	No. 7	47 FR 45589, 10/13/82. 48 FR 37526, 08/18/83. 51 FR 8243, 03/10/86. 52 FR 12084, 04/14/87. 59 FR 46439, 09/08/94. 65 FR 46997, 08/01/00. 72 FR 69723, 12/10/07.
60–0010—Hearing Office Tracking System of Claimant Cases	No. 7	71 FR 1806, 01/11/06. 72 FR 69723, 12/10/07.
60–0012—Listing and Alphabetical Name File (Folder) of Vocational Experts, Medical Experts And Other Health Care/Non-Health Care Professionals Experts (Medicare).	No. 10	76 FR 24557, 05/02/11.
60–0013—Records of Usage of Medical Experts, Vocational Experts, and Other Health Care/Non-Health Care Professionals Experts (Medicare).	No. 8	71 FR 1809, 01/11/06. 72 FR 69723, 12/10/07.
60–0014—Curriculum Vitae and Professional Qualifications of Medical Advisors, and Resumes of Vocational Experts.	No. 9	47 FR 45589, 10/13/82. 48 FR 37526, 08/18/83. 51 FR 8243, 03/10/86. 52 FR 12084, 04/14/87. 59 FR 46439, 09/08/94. 72 FR 69723, 12/10/07.
60–0038—Employee Building Pass Files	No. 8	47 FR 45606, 10/13/82. 48 FR 37526, 08/18/83. 51 FR 8243, 03/10/86. 52 FR 12084, 04/14/87. 59 FR 46439, 09/08/94. 72 FR 69723, 12/10/07.
60–0040—Quality Review System	No. 14	47 FR 45606, 10/13/82. 48 FR 37526, 08/18/83. 51 FR 8243, 03/10/86. 52 FR 12084, 04/14/87. 59 FR 46439, 09/08/94. 65 FR 46997, 08/01/00. 72 FR 69723, 12/10/07.
60–0042—Quality Review Case Files	No. 14	47 FR 45607, 10/13/82. 48 FR 37526, 08/18/83. 51 FR 8243, 03/10/86. 52 FR 12084, 04/14/87. 59 FR 46439, 09/08/94. 65 FR 46997, 08/01/00. 72 FR 69723, 12/10/07.
60–0044—National Disability Determination Services	No. 12	71 FR 11810, 01/11/06. 72 FR 69723, 12/10/07.
60–0045—Black Lung Payment System	No. 17	52 FR 9543, 03/25/87. 59 FR 46439, 09/08/94. 60 FR 52948, 10/11/95. 72 FR 69723, 12/10/07.
60–0046—Disability Determination Service Consultant's File	No. 8	71 FR 1812, 01/11/06. 72 FR 69723, 12/10/07.
60–0050—Completed Determination Record—Continuing Disability Determinations	No. 11	71 FR 1814, 01/11/06. 72 FR 69723, 12/10/07.
60–0057—Quality Evaluation Data Records	No. 6	47 FR 45615, 10/13/82. 48 FR 37526, 08/18/83. 51 FR 8243, 03/10/86. 52 FR 12084, 04/14/87. 59 FR 46439, 09/08/94. 65 FR 46997, 08/01/00. 72 FR 69723, 12/10/07.
60–0058—Master Files of Social Security Number Holders and SSN Applications	No. 50	75 FR 82121, 12/29/10. 78 FR 40542, 07/05/13. 79 FR 78780, 02/13/14. 83 FR 31250, 07/03/18. 83 FR 31252, 07/03/18.
60–0059–Earnings Recording and Self-Employment Income System	No. 35	71 FR 1819, 01/11/06. 78 FR 40542, 07/05/13.
60–0063—Resource Accounting System	No. 7	47 FR 45620, 10/13/82. 48 FR 37526, 08/18/83. 51 FR 8243, 03/10/86.

System No. and name	New routine use	Federal Register citation No./ publication date
		52 FR 12084, 04/14/87.
		59 FR 46439, 09/08/94.
		65 FR 46997, 08/01/00.
		72 FR 69723, 12/10/07.
60–0077—Congressional Inquiry File	No. 8	71 FR 1823, 01/11/06.
		72 FR 69723, 12/10/07.
60–0078—Public Inquiry Correspondence File	No. 9	71 FR 1823, 01/11/06.
		72 FR 69723, 12/10/07.
60–0089—Claims Folders System	No. 38	68 FR 15784, 04/01/03.
		72 FR 69723, 12/10/07.
		83 FR 31250, 07/03/18.
60–0090—Master Beneficiary Record	No. 43	71 FR 1829, 01/11/06.
		72 FR 69723, 12/10/07.
		78 FR 40542, 07/05/13.
		83 FR 31250, 07/03/18.
		83 FR 31252, 07/03/18.
60–0094—Recovery of Overpayments, Accounting and Reporting	No. 12	70 FR 49354, 08/23/05.
		72 FR 69723, 12/10/07.
		83 FR 31250, 07/03/18.
60–0103—Supplemental Security Income Record	No. 41	71 FR 1830, 01/11/06.
		72 FR 69723, 12/10/07.
		83 FR 31250, 07/03/18.
		83 FR 31252, 07/03/18.
60–0104—Race and Ethnicity Collection System (RECS)	No. 10	74 FR 42727, 08/24/09.
60–0118—Non-Contributory Military Service Reimbursement System	No. 7	71 FR 1834, 01/11/06.
		72 FR 69723, 12/10/07.
60–0159—Continuous Work History Sample (Statistics)	No. 6	47 FR 45643, 10/13/82.
		65 FR 46997, 08/01/00.
		72 FR 69723, 12/10/07.
60–0186—Civil Action Tracking System (CATS)	No. 7	70 FR 60383, 10/17/05.
		72 FR 69723, 12/10/07.
60–0196—Disability Studies, Surveys, Records and Extracts (Statistics)	No. 5	57 FR 55265, 11/24/92.
		65 FR 46997, 08/01/00.
		72 FR 69723, 12/10/07.
60–0199—Extramural Surveys (Statistics)	No. 5	71 FR 1835, 01/11/06.
		72 FR 69723, 12/10/07.
60–0200—Retirement and Survivors Studies, Surveys, Records and Extracts (Statistics)	No. 4	47 FR 45649, 10/13/82.
		65 FR 46997, 08/01/00.
		72 FR 69723, 12/10/07.
60–0202—Old Age, Survivors and Disability Beneficiary and Worker Records and Extracts (Statistics).	No. 6	47 FR 45650, 10/13/82.
		69 FR 11693, 08/01/00.
		69 FR 11693, 03/11/04.
		72 FR 69723, 12/10/07.
60–0203—Supplemental Security Income Studies, Surveys, Records and Extracts (Statistics)	No. 5	47 FR 45651, 10/13/82.
		65 FR 46997, 08/01/00.
		72 FR 69723, 12/10/07.
60–0210—Record of Individuals Authorized Entry to Secured Automated Data Processing Area	No. 8	47 FR 51795, 11/17/85.
		51 FR 8243, 03/10/86.
		52 FR 12084, 04/14/87.
		59 FR 46439, 09/08/94.
		72 FR 69723, 12/10/07.
60–0211—Beneficiary, Family and Household Surveys, Records and Extracts System (Statistics)	No. 6	48 FR 51693, 11/10/83.
		65 FR 46997, 08/01/00.
		69 FR 11693, 03/11/04.
		72 FR 69723, 12/10/07.
60–0213—Quality Review of Hearing/Appellate Process	No. 9	47 FR 45655, 10/13/82.
		48 FR 37526, 08/18/83.
		51 FR 8243, 03/10/86.
		52 FR 12084, 04/14/87.
		59 FR 46439, 09/08/94.
		65 FR 46997, 08/01/00.
		72 FR 69723, 12/10/07.
60–0214—Personal Identification Number File (PINFile)	No. 5	59 FR 46439, 09/08/94.
		72 FR 69723, 12/10/07.
60–0218—Disability Insurance and Supplemental Security Income Demonstration Projects and Experiments System.	No. 8	71 FR 1836, 01/11/06.
		72 FR 69723, 12/10/07.
60–0219—Representative Disqualification/Suspension Information System	No. 18	75 FR 25904, 05/10/10.
		80 FR 30969, 01/06/15.
60–0220—Kentucky Birth Records System	No. 6	52 FR 12084, 04/14/87.
		59 FR 46439, 09/08/94.
		72 FR 69723, 12/10/07.

System No. and name	New routine use	**Federal Register** citation No./ publication date
60–0221—Vocational Rehabilitation Reimbursement Case Processing System	No. 11	71 FR 1840, 01/11/06. 72 FR 69723, 12/10/07.
60–0224—SSA-Initiated Personal Earnings and Benefit Estimate Statement (SIPEBES) History File	No. 8	59 FR 54004, 10/27/94. 72 FR 69723, 12/10/07.
60–0225—SSA Initiated Personal Earnings and Benefit Estimate Statement Address System for Certain Territories.	No. 7	59 FR 54004, 10/27/94. 72 FR 69723, 12/10/07.
60–0228—Safety Management Information System (SSA Accident, Injury and Illness Reporting System).	No. 8	71 FR 1844, 01/11/06. 72 FR 69723, 12/10/07.
60–0230—Social Security Administration Parking Management Record System	No. 6	71 FR 1846, 01/11/06. 72 FR 69723, 12/10/07.
60–0231—Financial Transactions of SSA Accounting and Finance Offices	No. 20	71 FR 1847, 01/11/06. 72 FR 69723, 12/10/07.
60–0232—Central Registry of Individuals Doing Business With SSA (Vendor File)	No. 12	71 FR 1849, 01/11/06. 72 FR 69723, 12/10/07.
60–0234—Employee Assistance Program (EAP) Records	No. 8	71 FR 1851, 01/11/06. 72 FR 69723, 12/10/07.
60–0236—Employee Development Program Records	No. 14	71 FR 1853, 01/11/06. 72 FR 69723, 12/10/07.
60–0237—Employees' Medical Records	No. 9	71 FR 1854, 01/11/06. 72 FR 69723, 12/10/07.
60–0238—Pay, Leave and Attendance Records	No. 26	71 FR 1856, 01/11/06. 72 FR 69723, 12/10/07.
60–0239—Personnel Records in Operating Offices	No. 18	71 FR 1859, 01/11/06. 72 FR 69723, 12/10/07.
60–0241—Employee Suggestion Program Records New Routine Uses	No. 7	71 FR 1861, 01/11/06. 72 FR 69723, 12/10/07.
60–0244—Administrative Grievances Filed Under Part 771 of 5 CFR	No. 20	71 FR 1862, 01/11/06. 72 FR 69723, 12/10/07.
60–0245—Negotiated Grievance Procedure Records	No. 22	71 FR 1864, 01/11/06. 72 FR 69723, 12/10/07.
60–0250—Equal Employment Opportunity (EEO) Counselor and Investigator Personnel Records	No. 14	71 FR 1866, 01/11/06. 72 FR 69723, 12/10/07.
60–0255—Plans for Achieving Self-Support (PASS) Management Information System	No. 10	71 FR 1867, 01/11/06. 72 FR 69723, 12/10/07.
60–0259—Claims Under the Federal Tort Claims Act and Military Personnel and Civilian Employees' Claim Act.	No. 9	71 FR 1869, 01/11/06. 72 FR 69723, 12/10/07.
60–0262—Attorney Applicant Files	No. 8	71 FR 1871, 01/11/06. 72 FR 69723, 12/10/07.
60–0268—Medicare Part B Buy-In Information System	No. 10	64 FR 10173, 03/02/99. 72 FR 69723, 12/10/07.
60–0269—Prisoner Update Processing System (PUPS)	No. 13	64 FR 11076, 03/08/99. 72 FR 69723, 12/10/07. 78 FR 40542, 07/05/13.
60–0270—Records of Individuals Authorized Entry into Secured Areas by Digital Lock Systems, Electronic Key Card Systems or Other Electronic Access Devices.	No. 6	65 FR 77953, 12/13/00. 72 FR 69723, 12/10/07.
60–0273—Social Security Title VIII Special Veterans Benefits Claims Development and Management Information System.	No. 16	65 FR 13803, 03/14/00. 65 FR 46997, 08/01/00. 72 FR 69723, 12/10/07.
60–0274—Litigation Docket and Tracking System	No. 12	71 FR 1872, 01/11/06. 72 FR 69723, 12/10/07.
60–0275—Civil Rights Complaints Filed by Members of the Public	No. 10	71 FR 1874, 01/11/06. 72 FR 69723, 12/10/07.
60–0276—Social Security Administration's (SSA's) Talking and Listening to Customers (TLC)	No. 7	65 FR 48272, 08/07/00. 72 FR 69723, 12/10/07.
60–0279—Social Security Administration's (SSA's) Mandate Against Red Tape (SMART)	No. 8	65 FR 49047, 08/10/00. 72 FR 69723, 12/10/07.
60–0280—SSA Administrative Sanctions	No. 7	65 FR 54595, 09/08/00. 72 FR 69723, 12/10/07.
60–0290—Social Security Administration's Customer PIN/Password (PPW) Master File System	No. 8	71 FR 1874, 01/11/06. 72 FR 69723, 12/10/07.
60–0295—Ticket-to-Work and Self-Sufficiency Program Payment Database	No. 9	66 FR 17985, 04/04/01. 72 FR 69723, 12/10/07.
60–0300—Ticket-to-Work Program Manager (PM) Management Information System	No. 9	66 FR 32656, 06/15/01. 72 FR 69723, 12/10/07.
60–0305—SSA Mass Transportation Subsidy Program System	No. 13	67 FR 44658, 07/03/02. 72 FR 69723, 12/10/07.
60–0310—Medicare Savings Programs Information System	No. 10	69 FR 17019, 03/31/04. 72 FR 69723, 12/10/07.
60–0315—Reasonable Accommodation for Persons with Disabilities (RAPD)	No. 12	70 FR 62157, 10/25/05. 72 FR 69723, 12/10/07.

System No. and name	New routine use	Federal Register citation No./ publication date
60–0318—Representative Payee/Misuse Restitution Control System (RP/MRCS)	No. 11	70 FR 29547, 05/23/05. 72 FR 69723, 12/10/07. 83 FR 31250, 07/03/18.
60–0320—Electronic Disability Claim File (eDib)	No. 32	68 FR 71210, 12/22/03. 72 FR 69723, 12/10/07.
60–0321—Medicare Part D and Part D Subsidy File	No. 23	71 FR 42159, 07/25/06. 72 FR 69723, 12/10/07.
60–0325—Appointed Representatives File	No. 14	74 FR 51940, 10/08/09.
60–0328—National Docketing Management Information System (NDMIS)	No. 14	70 FR 34515, 06/14/05. 70 FR 36224, 06/22/05. 72 FR 69723, 12/10/07.
60–0330—eWork	No. 11	68 FR 45037, 09/15/03. 72 FR 69723, 12/10/07.
60–0340—Freedom of Information Act (FOIA) and Privacy Act Record Request and Appeal System.	No. 11	81 FR 45352, 07/13/16.
60–0350—Visitor Intake Process/Customer Service Record (VIP/CSR) System	No. 9	72 FR 71470, 12/17/07.
60–0355—The Non-Attorney Representative Prerequisites Process File (NARPPF)	No. 12	69 FR 77823, 12/28/04. 72 FR 69723, 12/10/07.
60–0356—Administrative Law Judge/Public Alleged Misconduct Complaints (ALJ/PAMC)	No. 15	75 FR 8171, 02/23/10.
60–0360—Identity Protection Program (IPP) System	No. 12	73 FR 15828, 03/25/08.
60–0361—Identity Management System (IDMS)	No. 16	71 FR 64751, 11/03/06. 72 FR 69723, 12/10/07.
60–0362—Recordings of Service Operations	No. 13	73 FR 16408, 03/27/08.
60–0363—Call Detail Management Information Report	No. 13	71 FR 16408, 03/27/08.
60–0364—Service Operation Database	No. 13	73 FR 16408, 03/27/08.
60–0370—The Representative Payee and Beneficiary Survey Data System	No. 7	71 FR 16397, 03/31/06. 72 FR 69723, 12/10/07.
60–0371—Social Security Administration Unified Measurement System/Managerial Cost Accountability (SUMS/MCAS).	No. 13	73 FR 5619, 01/30/08.
60–0372—Economic Recovery List (ERL) Database	No. 13	75 FR 40014, 07/13/10.
60–0373—Repository of Electronic Authentication Data Master File	No. 9	75 FR 79065, 12/19/10.
60–0378—Requests for Accommodation from Members of the Public (RAMP)	No. 12	79 FR 34558, 06/17/14.
60–0380—Anti-Harassment & Hostile Work Environment Case Tracking and Records System	No. 14	81 FR 87119, 12/02/16.

SSA is not republishing the system of records notices in their entirety. Instead, SSA is republishing only the identification number, the name of the system of record, the number of the new routine use, and the issue of the **Federal Register** in which the system notice was last published in full, including the subsequent modification to the system of records notice's publication date and page number.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

SSA provides the address of the component and system manager responsible for each system in the **Federal Register** notice listed above.

SYSTEM MANAGER(S):

SSA provides the title, business address, and contact information of the agency official who is responsible for the system in the **Federal Register** notice listed above.

HISTORY:

SSA provides the citation to the last full **Federal Register** notice, as well as last subsequent modification notice to the system of records notice above.

In accordance with 5 U.S.C. 552a(r), SSA provided a report to OMB and Congress on this modification to our system of records.

Dated: August 16, 2018.

Mary Zimmerman,

Acting Executive Director, Office of Privacy and Disclosure, Office of the General Counsel.

[FR Doc. 2018–23905 Filed 10–31–18; 8:45 am]

BILLING CODE P

DEPARTMENT OF STATE

[Public Notice 10596]

Notice of Public Meeting Shipping Coordination Committee Meeting

The Department of State will conduct an open meeting at 9 a.m. on November 27, 2018, in the CDR Raymond J. Evans Conference Center, Room 6i10–01–a, of the Douglas A. Munro Coast Guard Headquarters Building at St. Elizabeth's, 2703 Martin Luther King Jr. Avenue SE, Washington DC 20593. The primary purpose of the meeting is to prepare for the one-hundredth session of the International Maritime Organization's (IMO) Maritime Safety Committee to be held at the IMO Headquarters, United Kingdom, December 3–7, 2018.

The agenda items to be considered include:

—Adoption of the agenda; report of credentials
—Decisions of other IMO bodies
—Consideration and adoption of amendments to mandatory instruments
—Measures to enhance maritime security
—Regulatory scoping exercise for the use of Maritime Autonomous Surface Ships (MASS)
—Goal-based new ship construction standards
—Safety measures for non-SOLAS ships operating in polar waters
—Pollution prevention and response (matters emanating from the fifth session of the Sub-Committee)
—Ships systems and equipment (report of the fifth session of the Sub-Committee)
—Human element, training and watchkeeping (report of the fifth session of the Sub-Committee)
—Carriage of cargoes and containers (urgent matters emanating from the fifth session of the Sub-Committee)
—Implementation of IMO instruments (urgent matters emanating from the fifth session of the Sub-Committee)

—Capacity building for the implementation of new measures

—Piracy and armed robbery against ships

—Unsafe mixed migration by sea

—Application of the Committee's method of work

—Work programme

—Election of the Chair and Vice-Chair for 2019

—Any other business

—Consideration of the report of the Committee on its one-hundredth session

Members of the public may attend this meeting up to the seating capacity of the room. Upon request to the meeting coordinator, members of the public may also participate via teleconference, up to the capacity of the teleconference phone line. To access the teleconference line, participants should call (202) 475–4000 and use Participant Code: 887 809 72. To facilitate the building security process, and to request reasonable accommodation, those who plan to attend should contact the meeting coordinator, LCDR Staci Weist, by email at *Eustacia.Y.Weist@uscg.mil,* by phone at (202) 372–1376, or in writing at 2703 Martin Luther King Jr. Ave. SE, Stop 7509, Washington, DC 20593–7509 not later than November 21, 2018, 5 days prior to the meeting. Requests made after November 21, 2018 might not be able to be accommodated. Please note that due to security considerations, two valid, government issued photo identifications must be presented to gain entrance to the Coast Guard Headquarters building. It is recommended that attendees arrive no later than 30 minutes ahead of the scheduled meeting for the security screening process. The Headquarters building is accessible by taxi, public transportation, and privately owned conveyance (upon request for parking). Please contact the meeting coordinator if you plan to participate by phone.

Additional information regarding this and other public meetings may be found at *https://www.dco.uscg.mil/IMO/.*

Gregory J. O'Brien,

Executive Secretary, Shipping Coordinating Committee, Office of Ocean and Polar Affairs, Department of State.

[FR Doc. 2018–23865 Filed 10–31–18; 8:45 am]

BILLING CODE 4710–09–P

DEPARTMENT OF STATE

[Public Notice: 10520]

60-Day Notice of Proposed Information Collection: Risk Analysis and Management (RAM)

ACTION: Notice of request for public comment.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. 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 60 days for public comment preceding submission of the collection to OMB.

DATES: The Department will accept comments from the public up to December 31, 2018.

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

- *Web:* Persons with access to the internet may comment on this notice by going to *www.Regulations.gov*. You can search for the document by entering ''Docket Number: DOS–2018–0035'' in the Search field. Then click the ''Comment Now'' button and complete the comment form.
- *Email: FARRELLLM1@state.gov.*
- *Regular Mail:* Send written comments to: U.S. Department of State, Office of Risk Analysis and Management, 2201 C St. NW, Washington, DC 20520.
- *Fax:* 202–663–1037.
- *Hand Delivery or Courier:* U.S. Department of State, Office of Risk Analysis and Management, 2201 C St. NW, Washington, DC 20520.

You must include the DS form number (if applicable), information collection title, and the OMB control number in any correspondence.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Lisa M. Farrell, U.S. Department of State, Office of Risk Analysis and Management, 2201 C Street NW, Washington, DC 20520; who may be reached on 202–647–6020 or at *FARRELLLM1@state.gov.*

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Risk Analysis and Management.
- *OMB Control Number:* 1405–0204.
- *Type of Request:* Revision of a Currently Approved Collection.
- *Originating Office:* Bureau of Administration, Office of the Procurement Executive (A/OPE).
- *Form Number:* DS–4184.
- *Respondents:* Potential Contractors and Grantees.
- *Estimated Number of Respondents:* 500.
- *Estimated Number of Responses:* 500.
- *Average Time per Response:* 1 hour 30 minutes.
- *Total Estimated Burden Time:* 750 hours.
- *Frequency:* On occasion.
- *Obligation to Respond:* Voluntary.

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 information collected from individuals and organizations is used to conduct screening to ensure that State funded activities do not provide support to entities or individuals deemed to be a risk to national security.

The State Department has implemented a Risk Analysis and Management Program to vet potential contractors and grantees seeking funding from the Department of State to mitigate the risk that such funds might benefit entities or individuals who present a national security risk. To conduct this vetting program the Department collects information from contractors, sub-contractors, grantees and sub-grantees regarding their directors, officers and/or key employees. The information collected is compared to information gathered from commercial, public, and U.S. government databases to determine the risk that the applying organization, entity or individual might use Department funds or programs in a way

that presents a threat to national security. The program is currently operating on a pilot basis consistent with the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2018 (Div. K, Pub. L. 115–141).

Methodology

The Department collects information through mail, fax, or electronic submission.

Cathy J. Read,

Procurement Executive, Bureau of Administration, Department of State.

[FR Doc. 2018–23842 Filed 10–31–18; 8:45 am]

BILLING CODE 4710–24–P

DEPARTMENT OF STATE

[Public Notice: 10597]

Notice of Determinations; Culturally Significant Objects Imported for Exhibition—Determinations: ''Play It Loud: Instruments of Rock & Roll'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects to be included in the exhibition ''Play It Loud: Instruments of Rock & Roll,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at The Metropolitan Museum of Art, New York, New York, from on or about April 1, 2019, until on or about September 15, 2019, at the Rock & Roll Hall of Fame, Cleveland, Ohio, from on or about November 20, 2019, until on or about September 13, 2020, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Elliot Chiu, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, and Delegation of Authority No. 236–3 of August 28, 2000.

Marie Therese Porter Royce,

Assistant Secretary for Educational and Cultural Affairs, Department of State.

[FR Doc. 2018–23902 Filed 10–31–18; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2018–87]

Petition for Exemption; Summary of Petition Received; The Boeing Company

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

ACTION: Notice.

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, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before November 21, 2018.

ADDRESSES: Send comments identified by docket number FAA–2018–0911 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, 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 20590–0001, 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 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Miles Anderson (202) 267–8624, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on October 29, 2018.

Lirio Liu,

Executive Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2018–0911.

Petitioner: The Boeing Company.

Section(s) of 14 CFR Affected: § 91.527(a).

Description of Relief Sought: The Boeing Company seeks an exemption from § 91.527(a) at amendment 91–310 with respect to operating the 777–9 and 777–8 ''777X'' series aircraft in icing conditions. This exemption would permit The Boeing Company to operate such aircraft within the holdover times of the other critical surfaces of the aircraft without specific consideration of the folding wingtip (FWT) conditions. The exemption would be limited by the Airplane Flight Manual (AFM)—Miscellaneous Limitations notation that defines conditions under which takeoff without appropriate de/anti-icing treatment of the FWT is not permitted.

[FR Doc. 2018–23886 Filed 10–31–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2018–0175]

Hours of Service of Drivers: American Concrete Pumping Association (ACPA); Application for Exemption

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to grant the American Concrete Pumping Association (ACPA) request for exemption from the requirement that short-haul drivers utilizing the records of duty status (RODS) exception return to their normal work-reporting location within 12 hours of coming on duty. The exemption enables all concrete pump operators, concrete pumping companies, and drivers who operate concrete pumps to use the short-haul exception but return to their work-reporting location within 14 hours instead of the usual 12 hours. FMCSA has analyzed the exemption application and the public comments and has determined that the exemption, subject to the terms and conditions imposed, will achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption.

DATES: This exemption is effective November 1, 2018 and expires October 31, 2023.

FOR FURTHER INFORMATION CONTACT: For information concerning this notice, please contact Ms. Pearlie Robinson, FMCSA Driver and Carrier Operations Division; Telephone: (202) 366–4225; Email: *MCPSD@dot.gov.* If you have questions on viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *www.regulations.gov* and insert the docket number, FMCSA–2018–0175 in the ''Keyword'' box and click ''Search.'' Next, click the ''Open Docket Folder'' button and choose the document to review. If you do not have access to the internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315 to grant exemptions from certain Federal Motor Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must also provide an opportunity for public comment on the request.

The Agency reviews safety analyses and public comments submitted, and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305). The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)) with the reasons for denying or granting the application and, if granted, the name of the person or class of persons receiving the exemption, and the regulatory provision from which the exemption is granted. The notice must also specify the effective period (up to 5 years) and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.300(b)) exemption may be renewed (49 CFR 381.300(b)).

III. Request for Exemption

ACPA seeks an exemption from the restriction of the RODS exception for short-haul drivers who return to their normal work reporting location and are released from work within 12 hours [49 CFR 395.1(e)(1)(ii)(A)]. Specifically, ACPA requests that concrete pump operators be treated the same as drivers operating ready-mixed concrete delivery vehicles as provided in 49 CFR 395.1(e)(1)(ii)(B). Section 395.1(e)(1)(ii)(B) allows drivers of ready-mixed concrete delivery vehicles to rely on the short-haul exception provided they return to their work-reporting locations and are released from work within 14 consecutive hours. The requested exemption would apply industry-wide to all concrete pump operators, concrete pumping companies, and drivers who deliver, set-up, and operate concrete pumps across the United States.

ACPA currently represents more than 600 member companies employing over 7,000 workers nationwide. The exemption would be applied to all interstate concrete pumper trucks and their operators. Although many of the trucks operate intrastate and would therefore not be covered by an FMCSA exemption, an unknown number of the pumping trucks are operated in metropolitan areas and do routinely cross State lines.[1]

ACPA explained that, like ready-mixed concrete delivery trucks and asphalt pavement delivery trucks, concrete pumps work with a perishable product delivered on a just-in-time basis. Timing and scheduling are critical to ensure a high-quality result. Allowing concrete pump drivers to use the short-haul exception, but return to their reporting location within 14 hours instead of 12 hours, would harmonize the hours-of-service rules for drivers of concrete pumps with the rules for drivers of the vehicles that supply the concrete.

ACPA explained that only a small percentage of the concrete pump operator's time is spent driving. On average, concrete pump operators spend between 25–32% of their time driving during a shift, and average daily driving distances are 20–25 miles. A pump operator has plenty of rest time with breaks ranging from 33%–55% of their total time pumping. The majority of an operator's time is spent waiting on ready-mixed concrete for them to pump.

ACPA further explained that a concrete pump cannot operate without concrete supplied by a ready-mixed truck. Having conflicting requirements creates confusion on job sites. Clear and consistent requirements between the concrete pumps and the ready-mixed trucks will help ensure an equivalent level of safety on the job site. ACPA adds that concrete pumping and placement companies work in collaboration with ready-mixed companies. Scheduling local business contracts in compliance with State and Federal regulations is complicated, given that some concrete companies operate under different FMCSA rules.

ACPA asserts that the concrete pumping industry has a solid safety record. Break periods, spent waiting for the ready-mixed truck deliveries, provide opportunity for concrete pump operators to rest and relax. The ACPA Operator Certification Program ensures, encourages, and educates the concrete pump operators on safe concrete pumping and placement procedures. These safety practices allow concrete operators to maintain their safety record through careful training and well-developed safety guidelines. Because of the concrete pump operators' training and preparation and numerous rest breaks, providing the additional 2 duty hours to concrete pump operators will have no impact on the level of safety provided under the short-haul exception. The requested exemption is for 5 years. A copy of the ACPA's

[1] FMCSA does not generally have jurisdiction over intrastate transportation; however, most States have commercial motor vehicle statutes and regulations that are compatible with Federal regulations. With few exceptions, an FMCSA exemption only applies to interstate transportation, although some States honor them for intrastate traffic.

application for exemption is available for review in the docket for this notice.

IV. Public Comments

On June 21, 2018, FMCSA published notice of this application and requested public comment (83 FR 28898). The Agency received four comments. One individual and the National Ready Mixed Concrete Association (NRMCA) filed comments in support of the proposed exemption. The Advocates for Highway and Auto Safety (Advocates) and the Alliance for Driver Safety & Security (Trucking Alliance) filed joint comments in opposition to the proposed exemption.

NRMCA wrote, ''As outlined in ACPA's request, due to the nature of concrete pump operators' schedules and inherent work practices that are closely aligned with the ready mixed concrete industry, NRMCA agrees that increasing the return to work-reporting location threshold from 12 to 14 hours would not diminish safety on our nation's roadways and ready mixed concrete construction sites.''

Mr. Jake Ford stated, ''I feel the FMCSA should look into expanding the 12-hour short-haul exemption to 14 hours to more than just Concrete Pumps. I work in the oilfield industry as a DOT/Fleet/Compliance Manager. Just like the concrete pump operators my drivers drive very little and spend 85% of their time on an oilfield service location operating equipment.''

''The Advocates and the Trucking Alliance oppose the ACPA Application for exemption on the grounds that the Application fails to meet the statutory and regulatory requirements of applications for exemption. The Application is defective in several respects since it does not justify the need for the exemption, does not access the safety impacts of the exemption, and does not explain or document how an equivalent level of safety would be achieved. All of which are statutory requirements of a valid exemption application.''

V. FMCSA Decision

FMCSA has evaluated ACPA's application and the public comments and decided to grant the exemption. The Agency believes that the exempted concrete pump drivers will likely achieve a level of safety that is equivalent to or greater than, the level of safety achieved without the exemption [49 CFR 381.305(a)]. The Agency granted similar exemptions to the National Asphalt Paving Association [January 26, 2018, (83 FR 3864)], and the Motion Picture Association of America [January 19, 2018, (83 FR 2869)]. In each of these situations, the driver spends relatively little time driving and is off duty for substantial periods of time during the day, making cumulative fatigue unlikely. In any case, a 14-hour driving window has been allowed for most drivers since early 2004, with no evidence of adverse effects. There is no reason to believe that the experience of drivers of concrete pump vehicles will be different.

VI. Terms and Conditions for the Exemption

(1) Drivers must return to the work reporting location and be released from work within 14 consecutive hours of coming on duty.

(2) Drivers must have a copy of this exemption document in their possession while operating under the terms of the exemption. The exemption document must be presented to law enforcement officials upon request.

(3) All motor carriers operating under this exemption must have a ''Satisfactory'' safety rating with FMCSA, or be ''unrated.'' Motor carriers with ''Conditional'' or ''Unsatisfactory'' FMCSA safety ratings are prohibited from using this exemption.

Extent of the Exemption

This exemption is limited to the provisions of 49 CFR 395.1(e)(1)(ii)(A). These drivers must comply will all other applicable provisions of the FMCSRs.

Preemption

In accordance with 49 U.S.C. 31313(d), as implemented by 49 CFR 381.600, during the period this exemption is in effect, no State shall enforce any law or regulation applicable to interstate commerce that conflicts with or is inconsistent with this exemption with respect to a firm or person operating under the exemption. States may, but are not required to, adopt the same exemption with respect to operations in intrastate commerce.

Notification to FMCSA

Any motor carrier utilizing this exemption must notify FMCSA within 5 business days of any accident (as defined in 49 CFR 390.5), involving any of the motor carrier's CMVs operating under the terms of this exemption. The notification must include the following information:

(a) Identity of the exemption: ''ACPA''

(b) Name of operating motor carrier and USDOT number,

(c) Date of the accident,

(d) City or town, and State, in which the accident occurred, or closest to the accident scene,

(e) Driver's name and license number and State of issuance

(f) Vehicle number and State license plate number,

(g) Number of individuals suffering physical injury,

(h) Number of fatalities,

(i) The police-reported cause of the accident,

(j) Whether the driver was cited for violation of any traffic laws or motor carrier safety regulations, and

(k) The driver's total driving time and total on-duty time period prior to the accident.

Reports filed under this provision shall be emailed to *MCPSD@DOT.GOV.*

Termination

FMCSA does not believe the drivers covered by this exemption will experience any deterioration of their safety record. However, should this occur, FMCSA will take all steps necessary to protect the public interest, including revocation of the exemption. The FMCSA will immediately revoke or restrict the exemption for failure to comply with its terms and conditions.

Issued on: October 25, 2018.

Raymond P. Martinez,

Administrator.

[FR Doc. 2018–23881 Filed 10–31–18; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request on Information Collection for Form 13768, Electronic Tax Administration Advisory Committee Membership Application

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently, the IRS is soliciting comments concerning Form 13768, Electronic Tax Administration Advisory Committee Membership Application.

DATES: Written comments should be received on or before December 31, 2018 to be assured of consideration.

ADDRESSES: Direct all written comments to Laurie Brimmer, Internal Revenue Service, Room 6529, 1111 Constitution Avenue NW, Washington, DC 20224. Please send separate comments for each specific information collection listed below. You must reference the information collection's title, form number, reporting or record-keeping requirement number, and OMB number (if any) in your comment.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the collection tools should be directed to Alissa Berry, at (901) 707–4988, at Internal Revenue Service, Room 6529, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Alissa.A.Berry@irs.gov* .

SUPPLEMENTARY INFORMATION: Currently, the IRS is seeking comments concerning the following information collection tools, reporting, and record-keeping requirements:

Title: Electronic Tax Administration Advisory Committee Membership.

OMB Number: 1545–2231.

Form Numbers: Form 13768.

Abstract: The Internal Revenue Service Restructuring and Reform Act of 1998 (RRA 98) authorized the creation of the Electronic Tax Administration Advisory Committee (ETAAC). ETAAC has a primary duty of providing input to the Internal Revenue Service (IRS) on its strategic plan for electronic tax administration. Accordingly, ETAAC's responsibilities involve researching, analyzing and making recommendations on a wide range of electronic tax administration issues.

Current Actions: There are no changes to the information collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 500.

Estimated Time per Response: 1 hour 30 minutes.

Estimated Total Annual Burden Hours: 750.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: October 29, 2018.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2018–23888 Filed 10–31–18; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF TREASURY

Internal Revenue Service

Office of the General Counsel; Appointment of Members of the Legal Division to the Performance Review Board, Internal Revenue Service

Under the authority granted to me as Acting Chief Counsel of the Internal Revenue Service by the General Counsel of the Department of the Treasury by General Counsel Directive 15, pursuant to the Civil Service Reform Act, I have appointed the following persons to the Legal Division Performance Review Board, Internal Revenue Service Panel:

1. Brian Callanan, Deputy General Counsel
2. David Horton, Commissioner (Tax Exempt and Government Entities), IRS
3. Mary Beth Murphy, Commissioner (Small Business and Self Employed), IRS

Alternate—Donna C. Hansberry, Chief (Appeals), IRS

This publication is required by 5 U.S.C. 4314(c)(4).

Dated: October 24, 2018.

William M. Paul,

Acting Chief Counsel, Internal Revenue Service.

[FR Doc. 2018–23878 Filed 10–31–18; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF TREASURY

Internal Revenue Service

Office of the General Counsel; Appointment of Members of the Legal Division to the Performance Review Board, Internal Revenue Service

Under the authority granted to me as Acting Chief Counsel of the Internal Revenue Service by the General Counsel of the Department of the Treasury by General Counsel Directive 15, pursuant to the Civil Service Reform Act, I have appointed the following persons to the Legal Division Performance Review Board, Internal Revenue Service Panel:

1. Chairperson, Drita Tonuzi, Deputy Chief Counsel (Operations)
2. Robin Greenhouse, Division Counsel (Large Business & International)
3. John Moriarty, Deputy Associate Chief Counsel (Income Tax and Accounting)
4. Marjorie Rollinson, Associate Chief Counsel (International)
5. Thomas Travers, Associate Chief Counsel (Finance & Management)

Alternate—Bruce Meneely, Division Counsel (Small Business & Self Employed)

This publication is required by 5 U.S.C. 4314(c)(4).

Dated: October 24, 2018.

William M. Paul,

Acting Chief Counsel, Internal Revenue Service.

[FR Doc. 2018–23877 Filed 10–31–18; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

Notice of Performance Review Board Members

AGENCY: Corporate Senior Executive Management Office, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Agencies are required to publish a notice in the **Federal Register** of the appointment of Performance Review Board (PRB) members. This notice announces the appointment of individuals to serve on the PRB of the Department of Veterans Affairs.

DATES: The appointments are effective as of October 26, 2018.

ADDRESSES: Corporate Senior Executive Management Office, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420.

FOR FURTHER INFORMATION CONTACT: Contact Tracey Therit, Acting Executive Director, Corporate Senior Executive Management Office (006D), Department of Veterans Affairs, 810 Vermont

Avenue NW, Washington, DC 20420, (202) 461–7865.

SUPPLEMENTARY INFORMATION: The membership of the Department of Veterans Affairs Performance Review Board is as follows:

Powers, Pamela J. (Chair)
Syrek, Christopher D.
Pape, Lisa M.
Breyfogle, Cynthia L.
Rivera, Fernando O.
Adelman, Michael D.
Streitberger, William F.
Mayes, Bradley G.
Sullivan, Matthew
Chandler, Richard C.
Johnson, Harvey W.
Pope, D. Brent
Murray, Edward J.
Oswalt, John D.
Seekins, DeAnne M.
Smith, Robert M.
McLenachen, David R.
Hogan, Michael R.
Parker, Amy L.
Milligan, Jeffrey
Orr, Martha

Signing Authority

The Secretary of Veterans Affairs 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. Robert L. Wilkie, Secretary, Department of Veterans Affairs, approved this document on October 24, 2018, for publication.

Authority: 5 U.S.C. 4314(c)(4)

Dated: October 24, 2018.

Jeffrey M. Martin,

Assistant Director, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

[FR Doc. 2018–23852 Filed 10–31–18; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 422, 423, 438, et al.
Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly, Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 422, 423, 438, and 498

[CMS–4185–P]

RIN 0938–AT59

Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare Advantage (MA) program (Part C) regulations and Prescription Drug Benefit program (Part D) regulations to implement certain provisions of the Bipartisan Budget Act of 2018; improve quality and accessibility; clarify certain program integrity policies; reduce burden on providers, MA plans, and Part D sponsors through providing additional policy clarification; and implement other technical changes regarding quality improvement. This proposed rule would also revise the appeals and grievances requirements for Medicaid managed care and MA special needs plans for dually eligible individuals to implement certain provisions of the Bipartisan Budget Act of 2018.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 31, 2018.

ADDRESSES: In commenting, please refer to file code CMS–4185–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4185–P, P.O. Box 8013, Baltimore, MD 21244–8013.

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–4185–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:
Theresa Wachter, (410) 786–1157, or Cali Diehl, (410) 786–4053, MA/Part C Issues.
Elizabeth Goldstein, (410) 786–6665, Parts C and D Quality Ratings Issues.
Mark Smith, (410) 786–8015, Prescription Drug Plan Access to Parts A and B Data Issues.
Vanessa Duran, (410) 786–8697, D–SNP Issues.
Frank Whelan, (410) 786–1302, Preclusion List Issues.
Jonathan Smith (410) 786–4671, or Joanne Davis, (410) 786–5127, MA RADV Issues.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments.

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

The primary purposes of this proposed rule are to: make revisions to the Medicare Advantage (MA) program (Part C) and Prescription Drug Benefit Program (Part D) regulations based on our continued experience in the administration of the Part C and Part D programs and to implement certain provisions of the Bipartisan Budget Act of 2018. The proposed changes are necessary to—

- Implement the Bipartisan Budget Act of 2018 provisions;
- Improve program quality and accessibility;
- Clarify program integrity policies; and
- Implement other changes.

This proposed rule would meet the Administration's priorities to reduce burden across the Medicare program by reducing unnecessary regulatory complexity, and improve the regulatory framework to facilitate development of Part C and Part D products that better meet the individual beneficiary's healthcare needs. Because the Bipartisan Budget Act of 2018 requires the Secretary to establish procedures, to the extent feasible, for integration and unification of the appeals and grievance processes for dually eligible beneficiaries who are enrolled in Medicaid and in MA special needs plans for dually eligible individuals, this proposed rule also includes proposals to revise the appeals and grievances requirements for Medicaid managed care and MA special needs plans for dually eligible individuals. We note CMS plans to release a proposed Medicare rule in the near future to further the President's agenda of reducing drug costs.

B. Summary of the Major Provisions

1. Requirements for Medicare Advantage Plans Offering Additional Telehealth Benefits (§§ 422.100, 422.135, 422.252, 422.254, and 422.264)

Section 50323 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123) created a new section 1852(m) of the Social Security Act (the Act), which allows MA plans to provide ''additional telehealth benefits'' to enrollees starting in plan year 2020 and treat them as basic benefits for purposes of bid submission and payment by CMS. The statute limits these authorized additional telehealth benefits to services for which benefits are available under Medicare Part B, but that are not payable under section 1834(m) of the Act and have been identified for the applicable year as clinically appropriate to furnish through electronic information and telecommunications technology (section 1852(m)(2)(A)(i) of the Act). Under this proposal, MA plans would be permitted to offer—as part of the basic benefit package—additional telehealth benefits beyond what is currently allowable under the original Medicare telehealth benefit. In addition, we propose to continue authority for

MA plans to offer supplemental benefits (that is, benefits not covered by original Medicare) via remote access technologies and/or telemonitoring for those services that do not meet the requirements for additional telehealth benefits.

Section 1852(m)(4) of the Act mandates that enrollee choice is a priority. If an MA plan covers a Part B service as an additional telehealth benefit, then the MA plan must also provide access to such service through an in-person visit and not only as an additional telehealth benefit. The enrollee must have the option whether to receive such service through an in-person visit or as an additional telehealth benefit. In addition, section 1852(m)(2)(A)(ii) of the Act excludes from additional telehealth benefits any capital and infrastructure costs and investments relating to such benefits. These statutory provisions have guided our proposal.

We propose to establish regulatory requirements that would allow MA plans to cover Part B benefits furnished through electronic exchange as ''additional telehealth benefits''—and as part of the basic benefits defined in § 422.101—instead of separate supplemental benefits. We believe additional telehealth benefits would increase access to patient-centered care by giving enrollees more control to determine when, where, and how they access benefits. We are soliciting comments from stakeholders on various aspects of our proposal, which would help inform CMS's next steps related to implementing the additional telehealth benefits.

2. Dual Eligible Special Needs Plans Provisions (§§ 422.2, 422.60, 422.102, 422.107, 422.111, 422.560 Through 422.562, 422.566, 422.629 Through 422.634, 422.752, 438.210, 438.400, and 438.402)

Section 50311(b) of the Bipartisan Budget Act of 2018 amends section 1859 of the Act to require integration of the Medicare and Medicaid benefits provided to enrollees in Dual Eligible Special Needs Plans (D–SNPs). In particular, the statute requires: (1) Development of unified grievance and appeals processes for D–SNPs; and (2) establishment of new standards for integration of Medicare and Medicaid benefits for D–SNPs.

The statute specifies a number of key elements for unified D–SNP grievance and appeals processes and grants the Secretary discretion to determine the extent to which unification of these processes is feasible. In particular, the unified processes must adopt the provisions from section 1852(f) and (g) of the Act (MA grievances and appeals) and sections 1902(a)(3) and (5), and 1932(b)(4) of the Act (Medicaid grievances and appeals, including managed care) that are most protective to the enrollee, take into account differences in state Medicaid plans to the extent necessary, be easily navigable by an enrollee, include a single written notification of all applicable grievance and appeal rights, provide a single pathway for resolution of a grievance or appeal, provide clear notices, employ unified timeframes for grievances and appeals, establish requirements for how the plan must process, track, and resolve grievances and appeals, and with respect to benefits covered under Medicare Parts A and B and Medicaid, incorporate existing law that provides continuation of benefits pending appeal for items and services covered under Medicare and Medicaid. The statute requires the Secretary to establish unified grievance and appeals procedures by April 1, 2020 and requires D–SNP contracts with state Medicaid agencies to use the unified procedures for 2021 and subsequent years.

With respect to the establishment of new standards for integration of Medicare and Medicaid benefits, the statute requires that all D–SNPs meet certain new minimum criteria for such integration for 2021 and subsequent years, either by covering Medicaid benefits through a capitated payment from a state Medicaid agency or meeting a minimum set of requirements as determined by the Secretary. The law also stipulates that for the years 2021 through 2025, if the Secretary determines that a D–SNP failed to meet one of these integration standards, the Secretary may impose an enrollment sanction, which would prevent the D–SNP from enrolling new members. In describing the ''additional minimum set of requirements'' established by the Secretary, the statute directs the Federally Coordinated Health Care Office in CMS to base such standards on ''input from stakeholders.'' We intend to use this rulemaking to solicit input from stakeholders on the implementation of these new statutory provisions as well as to clarify definitions and operating requirements for D–SNPs.

3. Medicare Advantage and Part D Prescription Drug Plan Quality Rating System (§§ 422.162(a) and 423.182(a), §§ 422.166(a) and 423.186(a), §§ 422.164 and 423.184, and §§ 422.166(i)(1) and 423.186(i)(1))

In the Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program Final Rule (hereafter referred to as the April 2018 final rule), CMS codified at §§ 422.160, 422.162, 422.164, and 422.166 (83 FR 16725 through 16731) and §§ 423.180, 423.182, 423.184, and 423.186 (83 FR 16743 through 16749) the methodology for the Star Ratings system for the MA and Part D programs, respectively. This was part of the Administration's effort to increase transparency and advance notice regarding enhancements to the Part C and D Star Ratings program. That final rule included mechanisms for the removal of measures for specific reasons (low statistical reliability and when the clinical guidelines associated with the specifications of measures change such that the specifications are no longer believed to align with positive health outcomes) but, generally, removal of a measure for other reasons would also occur through rulemaking.

At this time, we are proposing enhancements to the cut point methodology for non-Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures. We are also proposing substantive updates to the specifications for a few measures for the 2022 and 2023 Star Ratings, and rules for calculating Star Ratings in the case of extreme and uncontrollable circumstances. Unless otherwise stated, data would be collected and performance measured using these proposed rules and regulations for the 2020 measurement period and the 2022 Star Ratings.

4. Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE (§§ 422.222 and 423.120(c)(6))

In the April 2018 final rule, CMS removed several requirements pertaining to MA and Part D provider and prescriber enrollment that were to become effective on January 1, 2019. We stated in that final rule our belief that the best means of reducing the burden of the MA and Part D provider and prescriber enrollment requirements without compromising our payment safeguard objectives would be to focus on providers and prescribers that pose an elevated risk to Medicare beneficiaries and the Trust Funds. That is, rather than require the enrollment of MA providers and Part D prescribers regardless of the level of risk they might pose, we would prevent payment for MA items or services and Part D drugs that are, as applicable, furnished or prescribed by demonstrably problematic

providers and prescribers. Therefore, we established in the April 2018 final rule a policy under which: (1) Such problematic parties would be placed on a ''preclusion list''; and (2) payment for MA services and items and Part D drugs furnished or prescribed by these individuals and entities would be rejected or denied, as applicable. The MA and Part D enrollment requirements, in short, were replaced with the payment-oriented approach of the preclusion list.

This proposed rule would make several revisions and additions to the preclusion list provisions we finalized in the April 2018 final rule. We believe these changes would help clarify for stakeholders CMS' expectations with respect to the preclusion list.

5. Medicare Advantage Risk Adjustment Data Validation (RADV) Provisions (§§ 422.300, 422.310(e), and 422.311(a))

The Medicare Advantage Risk Adjustment Data Validation (RADV) program was implemented as the primary corrective action to reduce the Part C improper payment rate in compliance with the Improper Payments Information Act (IPIA) of 2002, as amended by the Improper Payments Elimination and Recovery Act (IPERA) of 2010 and updated by the Improper Payments Elimination and Recovery Improvement Act (IPERIA) of 2012. In this proposed rule, we would, based on longstanding case law and best practices from HHS and other federal agencies, establish that extrapolation may be utilized as a valid part of audit authority in Part C, as it has been historically a normal part of auditing practice throughout the Medicare program.

Accordingly, we are proposing the following:

- To establish that CMS would use extrapolation in RADV contract-level audits and that the extrapolation authority would apply to the payment year 2011 contract-level audits and all subsequent audits.
- Not to apply a fee-for-service (FFS) Adjuster to audit findings.

C. Summary of Costs and Benefits

BILLING CODE 4120–01–P

Provision	Description	Impact
Requirements for MA Plans Offering Additional Telehealth Benefits (§§ 422.100, 422.135, 422.252, 422.254, and 422.264)	Consistent with section 50323 of the Bipartisan Budget Act of 2018, we propose to allow MA plans to provide "additional telehealth benefits" to enrollees starting in plan year 2020 and treat them as basic benefits for purposes of bid submission and payment by CMS.	Additional telehealth benefits have the potential for significant savings and costs. Significant savings could arise from additional telehealth benefits being used for follow-up and monitoring to prevent future illness or from reduced travel time by enrollees to providers. However, additional telehealth benefits also could lead to an increase in provider visits in situations where face-to-face visits were not otherwise expected to occur. The quantification of these impacts are discussed under various assumptions in this proposed rule.
Integration Requirements for Dual Eligible Special Needs Plans (§§ 422.2, 422.60, 422.102, 422.107, 422.111, and 422.752)	Consistent with section 50311(b) of the Bipartisan Budget Act of 2018, we propose to establish, effective 2021, Medicare and Medicaid integration standards for MA organizations seeking to offer D-SNPs. Effective 2021 through 2025, we also propose to require the imposition of an intermediate sanction of prohibiting new enrollment into a D-SNP if CMS determines that the D-SNP is failing to comply with these integration standards. Finally, we propose to create new and modify existing regulatory definitions that relate to D-SNPs.	There would be a $3.4 million cost in the initial year to transition to the new requirements. After that, impact would be negligible.

Provision	Description	Impact
Unified Grievances and Appeals Procedures for Dual Eligible Special Needs Plans and Medicaid Managed Care Plans at the Plan Level (§§ 422.560 – 562, 422.566, 422.629 – 422.634, 438.210, 438.400, and 438.402)	Consistent with section 50311(b) of the Bipartisan Budget Act of 2018, we propose to unify Medicare and Medicaid grievance and appeals procedures for certain D-SNPs that enroll individuals who receive Medicare and Medicaid benefits from the D-SNP and a Medicaid managed care organization offered by the D-SNP's MA organization, the parent organization, or subsidiary owned by the parent organization. Medicare and Medicaid grievance and appeals processes differ in several key ways, which in effect creates unnecessary administrative complexity for health issuers participating across product lines. This proposal would allow enrollees to follow one resolution pathway at the plan level when filing a complaint or contesting an adverse coverage determination with their plan regardless of whether the matter involves a Medicare or Medicaid covered service.	The estimated cost impact in 2021 and subsequent years is $0.2 million.
MA and Part D Prescription Drug Plan Quality Rating System (§§ 422.162(a) and 423.182(a), 422.166(a) and 423.186(a), 422.164 and 423.184, and 422.166(i)(1) and 423.186(i)(1))	We are proposing several measure specification updates, adjustments for extreme and uncontrollable circumstances, and an enhanced cut point methodology. The measure changes are routine and do not have a significant impact on the ratings of contracts. The proposed policy for disasters would hold contracts harmless when there are extreme and uncontrollable circumstances affecting them. The proposed methodology to set Star Ratings cut points would help increase the stability and predictability of cut points from year to year.	Negligible impact.
Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE (§§ 422.222 and 423.120(c)(6))	We are proposing to make several revisions to the MA and Part D preclusion list policies that we finalized in the April 2018 final rule.	Negligible impact.

Provision	Description	Impact
MA Risk Adjustment Data Validation Provisions (§§ 422.300, 422.310(e), and 422.311(a))	We are proposing to establish that CMS would use extrapolation in RADV contract-level audits and that the extrapolation authority would apply to the payment year 2011 contract-level audits and all subsequent audits, and not to apply a FFS Adjuster to audit findings.	The estimated savings is $1 billion in 2020 to the Trust Fund, due to collections from industry of money improperly paid. In subsequent years the provision would save the Trust Fund at least $381 million each year. The savings result from the Trust Fund not making improper payments. Extrapolating audit findings does not increase the cost burden on the plan. The cost to the plan of complying with a RADV audit is neither the subject of nor affected by this provision. This provision addresses recovering extrapolated or non-extrapolated audit findings. While extrapolation does increase the level of the audit recovery, because returning improper payments is not a cost, the decision to extrapolate does not impact the cost to the plan.

BILLING CODE 4120–01–C

II. Provisions of the Proposed Regulations

A. Implementing the Bipartisan Budget Act of 2018 Provisions

1. Requirements for Medicare Advantage Plans Offering Additional Telehealth Benefits (§§ 422.100, 422.135, 422.252, 422.254, and 422.264)

Technologies that enable healthcare providers to deliver care to patients in locations remote from the providers (hereafter referred to as ''telehealth'') are increasingly being used to complement face-to-face patient-provider encounters. Telehealth visits among rural Medicare beneficiaries in particular have increased more than 25 percent a year for the past decade.[1] In MA, about 81 percent of MA plans offer supplemental telehealth benefits in the form of remote access technologies in 2018, an increase from 77 percent in 2017. These statistics show that the healthcare industry has made significant advances in technology that enable secure, reliable, real-time, interactive communication and data transfer that were not possible in the past. Moreover, the use of telehealth as a care delivery option for MA enrollees may improve access to and timeliness of needed care, increase convenience for patients, increase communication between providers and patients, enhance care coordination, improve quality, and reduce costs related to in-person care.[2]

MA basic benefits are structured and financed based on what is covered under Parts A and B (paid through the capitation rate by the government) with coverage of additional items and services and more generous cost sharing provisions financed as supplemental benefits (paid using rebate dollars or supplemental premiums paid by enrollees). Traditionally, MA plans have been limited in how they may deliver telehealth services outside of the original Medicare telehealth benefit under section 1834(m) of the the Act because of this financing structure; only services covered by original Medicare under Parts A and B, with actuarially equivalent cost sharing, are in the basic benefit bid paid by the capitation rate. Section 1834(m) of the Act and § 410.78 generally limit payment for telehealth services in original Medicare by authorizing payment only for specific services provided using an interactive audio and video telecommunications system that permits real-time communication between a Medicare beneficiary and a physician or certain other practitioner and by specifying

[1] Mehrotra, A., Jena, A., Busch, A., Souza, J., Uscher-Pines, L., Landon, B. (2016). ''Utilization of Telemedicine Among Rural Medicare Beneficiaries.'' *JAMA,* 315(18): 2015–2016.

[2] Medicare Payment Advisory Commission (MedPAC), *Report to the Congress: Medicare Payment Policy,* March 2018.

where the beneficiary may receive care (eligible originating sites). Originating sites generally are limited by both geography and patient setting. The statute grants the Secretary the authority to add to the list of allowable telehealth services based on an established annual process, but does not generally provide exceptions from the statutory limitations relating to geography or patient setting. Because sections 1852(a), 1853, and 1854 of the Act limit the basic benefits covered by the government's capitation payment to only Parts A and B services covered under original Medicare with actuarially equivalent cost sharing, telehealth benefits offered by MA plans in addition to those covered by original Medicare are currently offered as supplemental benefits and funded through the use of rebate dollars and/or supplemental premiums paid by enrollees.

On February 9, 2018, President Trump signed the Bipartisan Budget Act of 2018 (Pub. L. 115–123) into law. Section 50323 of the Bipartisan Budget Act of 2018 created a new section 1852(m) of the Act, which allows MA plans to provide ''additional telehealth benefits'' to enrollees starting in plan year 2020 and treat them as basic benefits (also known as ''original Medicare benefits'' or ''benefits under the original Medicare fee-for-service program option'') for purposes of bid submission and payment by CMS. The statute limits these authorized ''additional telehealth benefits'' to services for which benefits are available under Medicare Part B but that are not payable under section 1834(m) of the Act and have been identified for the applicable year as clinically appropriate to furnish through electronic information and telecommunications technology (hereinafter referred to as ''electronic exchange''). While MA plans have always been able to offer more telehealth services than are currently payable under original Medicare through supplemental benefits, this change in how such additional telehealth benefits are financed (that is, accounted for in the capitated payment) makes it more likely that MA plans will offer them and that more enrollees will use the benefit.

We are proposing to add a new regulation at § 422.135 to implement the new section 1852(m) of the Act and to amend existing regulations at §§ 422.100, 422.252, 422.254, and 422.264. Specifically, we propose to add a new regulation, to be codified at § 422.135, to allow MA plans to offer additional telehealth benefits, to establish definitions applicable to this new classification of benefits, and to enact requirements and limitations on them. Further, we are proposing to amend § 422.100(a) and (c)(1) to include additional telehealth benefits in the definition of basic benefits and add a cross-reference to new § 422.135 to reflect how these benefits may be provided as part of basic benefits. Finally, we are proposing to amend the bidding regulations at §§ 422.252, 422.254, and 422.264 to account for additional telehealth benefits in the basic benefit bid.

Under this proposal, MA plans will be permitted to offer—as part of the basic benefit package—additional telehealth benefits beyond what is currently allowable under the original Medicare telehealth benefit. According to § 422.100(a), MA plans are able to offer original Medicare telehealth benefits described in existing authority at section 1834(m) of the Act and § 414.65. We are proposing that in addition to original Medicare telehealth benefits, MA plans would be able (but not required) to offer additional telehealth benefits described in this proposed rule and at section 1852(m) of the Act. In addition, we propose to continue authority for MA plans to offer supplemental benefits (that is, benefits not covered by original Medicare) via remote access technologies and/or telemonitoring for those services that do not meet the requirements for additional telehealth benefits, such as the requirement of being covered by Part B when provided in-person. For instance, an MA plan may offer a videoconference dental visit to assess dental needs as a supplemental benefit because services primarily provided for the care, treatment, removal, or replacement of teeth or structures directly supporting teeth are not currently covered Part B benefits and thus would not be allowable as additional telehealth benefits.

We propose to establish regulatory requirements that would allow MA plans to cover Part B benefits furnished through electronic exchange as ''additional telehealth benefits''—and as part of the basic benefits defined in § 422.101—instead of separate supplemental benefits. We believe additional telehealth benefits would increase access to patient-centered care by giving enrollees more control to determine when, where, and how they access benefits.

Section 1852(m)(2)(A)(i) of the Act, as added by the Bipartisan Budget Act of 2018, defines additional telehealth benefits as services—(1) for which benefits are available under Part B, including services for which payment is not made under section 1834(m) of the Act due to the conditions for payment under such section; and (2) that are identified for the applicable year as clinically appropriate to furnish using electronic information and telecommunications technology when a physician (as defined in section 1861(r) of the Act) or practitioner (described in section 1842(b)(18)(C) of the Act) providing the service is not at the same location as the plan enrollee (which we refer to as ''through electronic exchange''). In addition, section 1852(m)(2)(A)(ii) of the Act excludes from additional telehealth benefits any capital and infrastructure costs and investments relating to such benefits. This statutory definition of ''additional telehealth benefits'' has guided our proposal.

We are proposing a new regulation at § 422.135 to authorize and govern the provision of additional telehealth benefits by MA organizations, consistent with our interpretation of the new statutory provision. First, we propose definitions for the terms ''additional telehealth benefits'' and ''electronic exchange'' in proposed regulation text at § 422.135(a). We propose to define ''additional telehealth benefits'' as services that meet the following: (1) Are furnished by an MA plan for which benefits are available under Medicare Part B but which are not payable under section 1834(m) of the Act; and (2) have been identified by the MA plan for the applicable year as clinically appropriate to furnish through electronic exchange. We propose to define ''electronic exchange'' as ''electronic information and telecommunications technology'' as this is a concise term for the statutory description of the means used to provide the additional telehealth benefits. We are not proposing specific regulation text that defines or provides examples of electronic information and telecommunications technology because the technology needed and used to provide additional telehealth benefits will vary based on the service being offered. Examples of electronic information and telecommunications technology (or ''electronic exchange'') may include, but are not limited to, the following: Secure messaging, store and forward technologies, telephone, videoconferencing, other internet-enabled technologies, and other evolving technologies as appropriate for non-face-to-face communication. We believe this broad and encompassing approach will allow for technological advances that may develop in the future and avoid tying the authority in the proposed new regulation to specific information formats or technologies that

permit non-face-to-face interactions for furnishing clinically appropriate services.

We are not proposing specific regulation text defining ''clinically appropriate,'' rather, we are proposing to implement the statutory requirement for additional telehealth benefits to be provided only when ''clinically appropriate'' to align with our existing regulations for contract provisions at § 422.504(a)(3)(iii), which requires each MA organization to agree to provide all benefits covered by Medicare ''in a manner consistent with professionally recognized standards of health care.'' We propose to apply the same principle to additional telehealth benefits, as additional telehealth benefits must be treated as if they were benefits under original Medicare per section 1852(m)(5) of the Act.

The statute limits additional telehealth benefits to those services that are identified for the applicable year as clinically appropriate to furnish through electronic exchange. The statute does not specify who or what entity identifies the services for the year. Therefore, we are proposing to interpret this provision broadly by not ourselves specifying the Part B services that an MA plan may offer as additional telehealth benefits for the applicable year, but instead allowing MA plans to independently determine which services each year are clinically appropriate to furnish in this manner. Thus, our proposed definition of additional telehealth benefits at § 422.135(a) provides that it is the MA plan (not CMS) that identifies the appropriate services for the applicable year. We believe that MA plans are in the best position to identify each year whether additional telehealth benefits are clinically appropriate to furnish through electronic exchange. MA plans have a vested interest in and responsibility for staying abreast of the current professionally recognized standards of health care, as these standards are continuously developing with new advancements in modern medicine. As professionally recognized standards of health care change over time and differ from practice area to practice area, our proposal is flexible enough to take those changes and differences into account.

Furthermore, § 422.111(b)(2) requires the MA plan to annually disclose the benefits offered under a plan, including applicable conditions and limitations, premiums and cost sharing (such as copayments, deductibles, and coinsurance) and any other conditions associated with receipt or use of benefits. MA plans satisfy this requirement through the Evidence of Coverage, or EOC, document provided to all enrollees. This disclosure requirement would have to include applicable additional telehealth benefit limitations. That is, any MA plan offering additional telehealth benefits must identify the services that can be covered as additional telehealth benefits when provided through electronic exchange. We believe that it is through this mechanism (the EOC) that the MA plan will identify each year which services are clinically appropriate to furnish through electronic exchange as additional telehealth benefits.

We solicit comment on this proposed implementation of the statute and our reasoning. We considered whether CMS should use the list of Medicare telehealth services payable by original Medicare under section 1834(m) of the Act as the list of services that are clinically appropriate to be provided through electronic exchange for additional telehealth benefits. In that circumstance, services on the list could be considered as clinically appropriate to be provided through electronic exchange for additional telehealth benefits without application of the location limitations of section 1834(m) of the Act. However, we did not believe that is the best means to take full advantage of the flexibility that Congress has authorized for the MA program. The list of Medicare telehealth services for which payment can be made under section 1834(m) of the Act under the original Medicare program includes services specifically identified by section 1834(m) of the Act as well as other services added to the Medicare telehealth list by CMS that meet certain criteria: (1) The services are similar to services currently on the list such that there are similar roles and interactions among the beneficiaries and the distant site physicians or practitioners furnishing the services; or (2) the services are not similar to services on the current list but are accurately described by the corresponding code when furnished via telehealth and produce demonstrated clinical benefit to patients when furnished using a telecommunications system. We believe these limitations and criteria do not apply to additional telehealth benefits under new section 1852(m) of the Act for MA plans.

The statute requires the Secretary to solicit comment on what types of items and services should be considered to be additional telehealth benefits. Therefore, we are also soliciting comments on whether we should place any limitations on what types of Part B items and services (for example, primary care visits, routine and/or specialty consultations, dermatological examinations, behavior health counseling, etc.) can be additional telehealth benefits provided under this authority.

An enrollee has the right to request additional telehealth benefits through the organization determination process. If an enrollee is dissatisfied with the organization determination, then the enrollee has the right to appeal the decision. We believe these rights help ensure access to medically necessary services, including additional telehealth benefits offered by an MA plan as proposed in this rule. In addition, CMS audits plan performance with respect to timeliness and clinical appropriateness of organization determinations and appeals.

While the MA plan would make the ''clinically appropriate'' decision in terms of coverage of an additional telehealth benefit, we note that each healthcare provider must also provide services that are clinically appropriate. We acknowledge that not all Part B items and services would be suitable for additional telehealth benefits because a provider must be physically present in order to properly deliver care in some cases (for example, hands-on examination, administering certain medications). Behavioral health, in particular, is a prime example of a service that could be provided remotely through MA plans' offering of additional telehealth benefits under this proposal. The President's Commission on Combating Drug Addiction and the Opioid Crisis recommends telehealth as useful in the effort to combat the opioid crisis, especially in geographically isolated regions and underserved areas where people with opioid use disorders and other substance use disorders may benefit from remote access to needed treatment.[3]

We are proposing in paragraph (b) the general rule to govern how an MA plan may offer additional telehealth benefits. Specifically, we propose that if an MA plan chooses to furnish additional telehealth benefits, the MA plan may treat these benefits as basic benefits covered under the original Medicare fee-for-service program as long as the requirements of proposed § 422.135 are met. We also propose in § 422.135(b) that if the MA plan fails to comply with the requirements of § 422.135, then the MA plan may not treat the benefits provided through electronic exchange as additional telehealth benefits, but may

[3] *https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Meeting%20Draft%20of%20Final%20Report%20-%20November%201%2C%202017.pdf.*

treat them as supplemental benefits. For example, a non-Medicare covered service provided through electronic exchange cannot be offered as an additional telehealth benefit because it does not comply with § 422.135, which is limited to furnishing through electronic exchange otherwise covered Part B covered services, but it may be offered it as a supplemental benefit.

Section 1852(m)(4) mandates that enrollee choice is a priority. If an MA plan covers a Part B service as an additional telehealth benefit, then the MA plan must also provide access to such service through an in-person visit and not only as an additional telehealth benefit. We propose to codify this statutory mandate preserving enrollee choice in regulation text at § 422.135(c)(1), which would require that the enrollee must have the option to receive a service that the MA plan would cover as an additional telehealth benefit either through an in-person visit or through electronic exchange. Section 1852(m)(5) of the Act mandates that additional telehealth benefits shall be treated as if they were benefits under the original Medicare fee-for-service program option. Based on the manner in which CMS currently allows differential cost sharing under MA plans for original Medicare-covered benefits, in proposed regulation text at § 422.135(f), we propose to allow MA plans to maintain different cost sharing for the specified Part B service(s) furnished through an in-person visit and the specified Part B service(s) furnished through electronic exchange. This aligns with how CMS has traditionally interpreted section 1852(a)(1)(B)(i), (iii), (iv), and (v) of the Act to mean that, subject to specific exceptions in the statute and § 422.100(j), basic benefits must be covered at an actuarially equivalent level of cost sharing from a plan level (that is, an aggregate and not enrollee level) perspective.

In proposed regulation text at § 422.135(c)(2), we propose to require MA plans to use their EOC (at a minimum) to advise enrollees that they may receive the specified Part B service(s) either through an in-person visit or through electronic exchange. Similarly, as we propose at § 422.135(c)(3), MA plans would have to use their provider directory to identify any providers offering services for additional telehealth benefits and in-person visits or offering services exclusively for additional telehealth benefits. We believe that these notifications in the EOC and the provider directory are important to ensure choice, transparency, and clarity for enrollees who might be interested in taking advantage of additional telehealth benefits. We request comments on what impact, if any, additional telehealth benefits should have on MA network adequacy policies. Specifically, we will look for the degree to which additional telehealth benefit providers should be considered in the assessment of network adequacy (including for certain provider types and/or services in areas with access concerns) and any potential impact on rural MA plans, providers, and/or enrollees.

Section 1852(m)(3) of the Act requires the Secretary to specify limitations or additional requirements for the provision or furnishing of additional telehealth benefits, including requirements with respect to physician or practitioner qualifications, factors necessary for the coordination of additional telehealth benefits with other items and services (including those furnished in-person), and other areas identified by the Secretary. We recognize the potential for additional telehealth benefits to support coordinated health care and increase access to care in both rural and urban areas. We expect MA plans will use these types of benefits to support an effective, ongoing doctor-patient relationship and the efficient delivery of needed care.

We propose in regulation text at § 422.135(c)(4) to require an MA plan offering additional telehealth benefits to comply with the provider selection and credentialing requirements provided in § 422.204. An MA plan must have written policies and procedures for the selection and evaluation of providers and must follow a documented process with respect to providers and suppliers, as described in § 422.204. Further, we propose that the MA plan, when providing additional telehealth benefits, must ensure through its contract with the provider that the provider meet and comply with applicable state licensing requirements and other applicable laws for the state in which the enrollee is located and receiving the service. We recognize, however, that it is possible for a state to have specific provisions regarding the practice of medicine using electronic exchange; our intent is to ensure that MA network providers comply with these laws and that MA organizations ensure compliance with such laws and only cover additional telehealth benefits provided in compliance with such laws. We solicit comment on whether to impose additional requirements for qualifications of providers of additional telehealth benefits, and if so, what those requirements should be.

In order to monitor the impact of the additional telehealth benefits on MA plans, providers, enrollees, and the MA program as a whole, we also propose to require MA plans to make information about coverage of additional telehealth benefits available to CMS upon request, per our proposed regulation text at § 422.135(c)(5). We propose that this information may include, but is not limited to, statistics on use or cost of additional telehealth benefits, manner(s) or method(s) of electronic exchange, evaluations of effectiveness, and demonstration of compliance with the requirements in proposed regulation text at § 422.135. The purpose of requiring MA plans to make such information available to CMS upon request is to determine whether CMS should make improvements to the regulation and/or guidance regarding additional telehealth benefits.

In proposed regulation text at § 422.135(d), we propose to require that MA plans furnishing additional telehealth benefits may only do so using contracted providers. We believe limiting service delivery of additional telehealth benefits to contracted providers offers MA enrollees access to these covered services in a manner more consistent with the statute because plans would have more control over how and when they are furnished. Additionally, MA plans' must have written policies and procedures for the selection and evaluation of providers. These policies must conform with MA credentialing requirements described in § 422.204. These policies would also provide additional oversight of providers' performance, increasing plans' ability to provide covered services such as additional telehealth benefits. We also propose to specify that if an MA plan covers benefits furnished by a non-contracted provider through electronic exchange, then those benefits may only be covered as a supplemental benefit, not an additional telehealth benefit (that is, not covered as a basic benefit). We request comment on whether the contracted providers' restriction should be placed on all MA plan types or limited only to certain plan types, such as local/regional preferred provider organization (PPO) plans, medical savings account (MSA) plans, and/or private fee-for-service (PFFS) plans. Currently, pursuant to § 422.4(a)(1)(v), PPO plans must provide reimbursement for all plan-covered medically necessary services received from non-contracted providers without prior authorization requirements. Without an opportunity to review the qualifications of the non-contracted

provider and to impose limits on how only clinically appropriate services are provided as additional telehealth benefits, PPO plans will not be able to meet the requirements in this proposed rule. Therefore, we are soliciting comment on whether to require just PPOs (and/or MSA plans, PFFS plans, etc.), instead of all MA plan types, to use only contracted providers for additional telehealth benefits.

Per section 1852(m)(2)(A)(ii) of the Act, the term ''additional telehealth benefits'' does not include capital and infrastructure costs and investments relating to such benefits. We propose to codify this requirement in § 422.254(b)(3)(i) as a restriction on how MA organizations include additional telehealth benefits in their bid submission. We believe that the statutory limit is tied only to the cost to the government of permitting coverage of these additional telehealth benefits as part of the bid for basic benefits. We are not proposing specific definitions of capital and infrastructure costs or investments related to such benefits at this time because the costs and investments needed and used to provide additional telehealth benefits will vary based on the individual MA plan's approach to furnishing the benefits and the MA plan's contracts with providers. Some examples of capital and infrastructure costs include, but are not limited to, high-speed internet installation and service, communication platforms and software, and video conferencing equipment. We are soliciting comments on what other types of capital and infrastructure costs and investments should be excluded from the bid and how CMS should operationalize this statutory requirement in the annual bid process. We propose to provide a more detailed list of examples in the final rule, based on feedback received from stakeholders.

In § 422.254(b)(3)(i), we propose that MA plans must exclude any capital and infrastructure costs and investments relating to additional telehealth benefits from their bid submission, for both additional telehealth services offered directly by the plan sponsor and services rendered by a third party provider. Accordingly, the projected expenditures in the MA bid for services provided via additional telehealth benefits must not include the corresponding capital and infrastructure costs. Any items provided to the enrollee in the administration of additional telehealth benefits must be directly related to the care and treatment of the enrollee for the Part B benefit. For example, MA plans may not provide enrollees with items such as internet service or permanently install telecommunication systems in an enrollee's home as part of administration of additional telehealth benefits.

In addition to our proposal at § 422.135, we also propose to amend paragraphs (a) and (c)(1) of § 422.100 to explicitly address how additional telehealth benefits may be offered by an MA plan. Section 1852(a)(1)(A) of the Act requires that each MA plan shall provide enrollees benefits under the original Medicare fee-for-service program option. As amended by the Bipartisan Budget Act of 2018, section 1852(a)(1)(B) of the Act defines ''benefits under the original Medicare fee-for-service program option'' to mean—subject to subsection (m) (regarding provision of additional telehealth benefits)—those items and services (other than hospice care or coverage for organ acquisitions for kidney transplants) for which benefits are available under Parts A and B to individuals entitled to benefits under Part A and enrolled under Part B. Since this definition is subject to the statutory provision for additional telehealth benefits, this means that all of the same coverage and access requirements that apply with respect to basic benefits also apply to any additional telehealth benefits an MA plan may choose to offer. Therefore, we propose to amend § 422.100(c)(1) to include additional telehealth benefits in the definition of basic benefits and to cross-reference the proposed regulation at § 422.135 that provides the rules governing additional telehealth benefits. We also propose to further clarify the regulation text in § 422.100(c)(1) to track the statutory language described earlier more closely in addressing both kidney acquisition and hospice in the definition of basic benefits. Finally, we propose to make corresponding technical revisions to § 422.100(a) to reference the new paragraph (c)(1) for basic benefits (clarifying that additional telehealth benefits are voluntary benefits for MA plans to offer—not required) and paragraph (c)(2) for supplemental benefits (instead of § 422.102 because supplemental benefits are listed as a benefit type in (c)(2)). We also propose a small technical correction in the last sentence of § 422.100(a) to replace the reference to § 422.100(g) with ''this section'' because there are a number of provisions in § 422.100—not just paragraph (g)—that are applicable to the benefits CMS reviews.

Additionally, we propose amendments to the bidding regulations at §§ 422.252, 422.254, and 422.264 to account for additional telehealth benefits and correct the inconsistent phrasing of references to basic benefits (for example, these regulations variously use the terms ''original Medicare benefits,'' ''benefits under the original Medicare program,'' ''benefits under the original Medicare FFS program option,'' etc.). In order to make the additional telehealth benefits part of the basic benefit bid and included in the ''monthly aggregate bid amount'' as part of the original Medicare benefits that are the scope of the basic benefit bid, we propose to update these various phrases to consistently use the phrase ''basic benefits as defined in § 422.100(c)(1).'' We also propose a few minor technical corrections to the bidding regulations. Finally, we propose a paragraph (e) in new § 422.135 to state that an MA plan that fully complies with § 422.135 may include additional telehealth benefits in its bid for basic benefits in accordance with § 422.254. This provision means that inclusion in the bid is subject to the bidding regulations we are also proposing to amend here.

In offering additional telehealth benefits, MA plans must comply with existing MA rules, including, but not limited to: Access to services at § 422.112; enrollee recordkeeping at § 422.118 (for example, confidentiality, accuracy, timeliness); standards for communications and marketing at § 422.2268 (for example, inducement prohibition); and non-discrimination at §§ 422.100(f)(2) and 422.110(a). Further, in addition to §§ 422.112, 422.118, 422.2268, 422.100(f)(2), and 422.110(a), MA plans must also ensure compliance with other federal non-discrimination laws, such as Title VI of the Civil Rights Act, section 504 of the Rehabilitation Act, and section 1557 of the Affordable Care Act. We are not proposing specific reference to these existing requirements in new § 422.135 because we do not believe that to be necessary. Compliance with these existing laws is already required; we merely note, as an aide to MA organizations, how provision of additional telehealth benefits must be consistent with these regulations. We solicit comment on this policy choice, specifically whether there are other existing regulations that CMS should revise to address their application in the context of additional telehealth benefits.

Finally, section 1852(m)(2)(B) of the Act instructs the Secretary to solicit comments on the implementation of these additional telehealth benefits by November 30, 2018; in addition to proposing regulations to implement section 1852(m) of the Act, we are using this notice of proposed rulemaking and the associated comment period to satisfy this statutory requirement. We thank

commenters in advance for their input to help inform CMS's next steps related to implementing the additional telehealth benefits.

2. Dual Eligible Special Needs Plans

Special needs plans (SNPs) are MA plans created by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) that are specifically designed to provide targeted care and limit enrollment to special needs individuals. Under the law, SNPs are able to restrict enrollment to: (1) Institutionalized individuals, who are defined in § 422.2 as those residing or expecting to reside for 90 days or longer in a long term care facility; (2) individuals entitled to medical assistance under a state plan under Title XIX; or (3) other individuals with certain severe or disabling chronic conditions who would benefit from enrollment in a SNP. As of June 2018, the CMS website listed 297 SNP contracts with 641 SNP plans that have at least 11 members. These figures included 190 Dual Eligible SNP contracts (D–SNPs) with 412 D–SNP plans with at least 11 members, 49 Institutional SNP contracts (I–SNPs) with 97 I–SNP plans with at least 11 members, and 58 Chronic or Disabling Condition SNP contracts (C–SNPs) with 132 C–SNP plans with at least 11 members. This proposed rule would implement the provisions of the Bipartisan Budget Act of 2018 that establish new requirements for D–SNPs for the integration of Medicare and Medicaid benefits and unification of Medicare and Medicaid grievance and appeals procedures that would be effective in 2021. This proposed rule would also clarify definitions and operating requirements for D–SNPs that would take effect on the effective date of the final rule.

a. Integration Requirements for Dual Eligible Special Needs Plans (§§ 422.2, 422.60, 422.102, 422.107, 422.111, and 422.752)

Beneficiaries who are dually eligible for both Medicare and Medicaid can face significant challenges in navigating the two programs, which include separate or overlapping benefits and administrative processes. Fragmentation between the two programs can result in a lack of coordination for care delivery, potentially resulting in—(1) missed opportunities to provide appropriate, high-quality care and improve health outcomes, and (2) ineffective care, such as avoidable hospitalizations and a poor beneficiary experience of care. Advancing policies and programs that integrate care for dual eligible individuals is one way in which we seek to address such fragmentation. Under plans that offer integrated care, dually eligible beneficiaries receive the full array of Medicaid and Medicare benefits through a single delivery system, thereby improving care coordination, quality of care, beneficiary satisfaction, and reducing administrative burden. Some studies have shown that highly integrated managed care programs perform well on quality of care indicators and enrollee satisfaction.[4]

D–SNPs are a type of MA plan that is intended to integrate or coordinate care for this population more effectively than standard M A plans or Original Medicare by focusing enrollment and care management on dually eligible individuals. As of June 2018, approximately 2.3 million dually eligible beneficiaries (one 1 of every 6 dually eligible beneficiaries) were enrolled in 412 D–SNPs. About 170,000 dually eligible beneficiaries are enrolled in fully integrated dual eligible special needs plans, or FIDE SNPs (that is, where the same organization receives capitation to cover both Medicare and Medicaid services).[5] Several states, including Arizona, Idaho, Hawaii, Massachusetts, Minnesota, New Jersey, New Mexico, New York, Pennsylvania, Tennessee, Texas, Virginia, and Wisconsin, operate Medicaid managed care programs for dually eligible individuals in which the state requires that the Medicaid managed care organizations serving dual eligible individuals offer a companion D–SNP product.

Since the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) first authorized D–SNPs' creation, subsequent legislation has been enacted that has extended their authority to operate and set forth additional programmatic requirements.

- Sections 164 and 165 of the Medicare Improvements for Patients and Providers Act (MIPPA) (Pub. L. 110–275) amended sections 1859 and 1852(a) of the Act to require D–SNPs to—
- Provide each prospective enrollee, prior to enrollment, with a comprehensive written statement that describes the benefits and cost-sharing protections to which the beneficiary is entitled under Medicaid and which are covered by the plan;
- Contract with the state Medicaid agency to provide benefits, or arrange for the provision of Medicaid benefits, which may include long-term care services consistent with state policy, to which such individual is entitled. Notwithstanding this requirement, section 164(c)(4) of MIPPA stipulated that a state is in no way obligated to contract with a D–SNP; and
- Limit the imposition of cost-sharing on full-benefit dual eligible individuals and Qualified Medicare Beneficiaries.
- Section 3205 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) revised section 1853(a)(1)(B) of the Act to permit the Secretary to apply a frailty payment under PACE payment rules to certain D–SNPs that are fully integrated with capitated contracts with states for Medicaid benefits, including long-term care, and that have similar average levels of frailty (as determined by the Secretary) as the PACE program.

Regulations promulgated following the enactment of these laws established provisions that:

- Define at § 422.2 a fully integrated special needs plan (FIDE SNP);
- Require at § 422.107 all MA organizations seeking to offer a D–SNP to enter into a contract containing a minimum set of terms and conditions with the state Medicaid agency;
- Require at § 422.111(b)(2)(iii) D–SNPs to furnish, prior to enrollment, certain benefit and cost-sharing information to dually eligible enrollees; and
- Permit at § 422.308(c)(4) the application of a frailty payment adjustment to FIDE SNPs that have a similar average level of frailty (as determined by the Secretary) as the PACE program.[6]

[4] *See:* Kim, H., Charlesworth, C.J., McConnell, K.J., Valentine, J.B., and Grabowski, DC (2017, November 15). *Comparing Care for Dual-Eligibles Across Coverage Models: Empirical Evidence From Oregon.* Retrieved from *http://journals.sagepub.com/doi/abs/10.1177/1077558717740206;* Anderson, W.L., Feng, Z., & Long, S.K. (2016, March 31). *Minnesota Managed Care Longitudinal Data Analysis,* prepared for the U.S. Department of Health and Human Services Assistant Secretary for Planning and Evaluation (ASPE). Retrieved from *https://aspe.hhs.gov/report/minnesota-managed-care-longitudinal-data-analysis;* Health Management Associates (2015, July 21). *Value Assessment of the Senior Care Options (SCO) Program.* Retrieved from *http://www.mahp.com/wp-content/uploads/2017/04/SCO-White-Paper-HMA–2015_07_20-Final.pdf;* and Medicare Payment Advisory Committee (2012, June 16). ''*Care coordination programs for dual-eligible beneficiaries.*'' In *June 2012 Report to Congress: Medicare and Health Care Delivery System.* Retrieved from *http://www.medpac.gov/docs/default-source/reports/chapter-3-appendixes-care-coordination-programs-for-dual-eligible-beneficiaries-june-2012-report-.pdf?sfvrsn=0.*

[5] Centers for Medicare & Medicaid Services (2018, June). *SNP Comprehensive Report.* Retrieved from *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data.html.*

[6] *See* 73 FR 54226 (September 18, 2008) and 76 FR 21432 (April 15, 2011)

Because the current regulations establish only minimum requirements, state Medicaid agencies may exercise authority to establish requirements that surpass the minimum, and to that end, we have seen states leverage their contracts with D–SNPs to limit D–SNP enrollment to individuals who also receive Medicaid benefits through the same organization, collect certain data from the D–SNP, and integrate beneficiary communication materials and care management processes to provide dual eligible enrollees a more seamless, coordinated experience of care.[7] CMS supports states that have an interest in pursuing integrated care models for dual eligible individuals, including through the use of their contracts with MA organizations offering D–SNPs, and currently provides technical assistance to states seeking to develop solutions tailored to their local market conditions, beneficiary characteristics, and policy environment.

Through this proposed rule, we are establishing new requirements in accordance with section 50311(b) of the Bipartisan Budget Act of 2018, which amended section 1859 of the Act to require that all D–SNPs meet certain new minimum criteria for Medicare and Medicaid integration for 2021 and subsequent years. Beyond the newly enacted amendments to the Act, we are also using this rulemaking to add requirements and clarifications to existing regulations to codify guidance and policy since D–SNPs were established nearly 15 years ago and to update certain aspects of the regulations. Under the newly enacted section 1859(f)(8)(D)(i) of the Act, the statute calls for D–SNPs, for 2021 and subsequent years, to meet one or more of three specified requirements, to the extent permitted under state law, for integration of benefits:

- A D–SNP must, in addition to meeting the existing requirement of contracting with the state Medicaid agency under section 1859(f)(3)(D) of the Act, coordinate long-term services and supports (LTSS), behavioral health services, or both, by meeting an additional minimum set of requirements for integration established by the Secretary based on input from stakeholders. Such requirements for integration could include: (1) Notifying the state in a timely manner of hospitalizations, emergency room visits, and hospital or nursing home discharges of enrollees; (2) assigning one primary care provider for each enrollee; or (3) data sharing that benefits the coordination of items and services under Medicare and Medicaid.
- A D–SNP must either—(1) meet the requirements of a fully integrated dual eligible special needs plan described in section 1853(a)(1)(B)(iv)(II) of the Act (other than the requirement that the plan have similar average levels of frailty as the PACE program); or (2) enter into a capitated contract with the state Medicaid agency to provide LTSS, behavioral health services, or both.
- The parent organization of a D–SNP that is also the parent organization of a Medicaid managed care organization providing LTSS or behavioral services must assume ''clinical and financial responsibility'' for benefits provided to beneficiaries enrolled in both the D–SNP and Medicaid managed care organization.

Section 50311(b) of the Bipartisan Budget Act of 2018 also authorizes the Secretary, in section 1859(f)(8)(D)(ii) of the Act, to impose an enrollment sanction on MA organizations offering a D–SNP that fails to meet at least one of these integration standards in plan years 2021 through 2025. In the event that the Secretary imposes such a sanction, the MA organization must submit to the Secretary a plan describing how it will come into compliance with the integration standards.

(1) Definitions of a ''Dual Eligible Special Needs Plan'', ''Fully Integrated Dual Eligible Special Needs Plan'', ''Highly Integrated Dual Eligible Special Needs Plan'', and ''Aligned Enrollment'' (§ 422.2)

We are proposing new definitions for the terms ''dual eligible special needs plan,'' ''fully integrated dual eligible special needs plan,'' ''highly integrated dual eligible special needs plan,'' and ''aligned enrollment,'' for purposes of part 422 (that is, the rules applicable to the MA program) and this proposed rule.

Through this notice of proposed rulemaking, we propose to consolidate statutory and regulatory references to a D–SNP and, in so doing, clearly state in § 422.2 the minimum requirements for a D–SNP. Currently, D–SNPs are described in various sections of 42 CFR part 422, including provisions governing the definition of specialized MA plans for special needs individuals in § 422.2, the supplemental benefit authority for D–SNPs that meet a high standard of integration and minimum performance and quality-based standards in § 422.102(e), state Medicaid agency contracting requirements in § 422.107, and specific benefit disclosure requirements in § 422.111(b)(2)(iii). In our proposed definition at § 422.2, we describe a dual eligible special needs plan as a type of specialized MA plan for individuals who are eligible for Medicaid under Title XIX of the Act that provides, as applicable, and coordinates the delivery of Medicare and Medicaid services, including LTSS and behavioral health services, for individuals who are eligible for such services; has a contract with the state Medicaid agency consistent with § 422.107 that meets the minimum requirements in paragraph (c) of such section; and satisfies at least one of following integration requirements: (1) It meets the additional state Medicaid agency contracting requirement at proposed § 422.107(d) (described in section II.A.2.a.(2)) of this proposed rule that surpasses the minimum requirements in current regulations at § 422.107(c); (2) it is a highly integrated dual eligible special needs plan (HIDE SNP), as described in further detail later in this section; or (3) it is FIDE SNP. In addition, we propose elsewhere in this proposed rule additional performance requirements for D–SNPs that we have not incorporated into the definition; for example, a D–SNP would provide assistance to individuals filing a grievance or appeal for a Medicaid services in accordance with proposed § 422.562(a)(5) (described in section II.A.2.b.(1) of this proposed rule).

While we do not explicitly cite or summarize the integration requirement at section 1859(f)(8)(D)(i)(III) of the Act in this proposed regulatory definition, we interpret the statutory language on assuming clinical and financial responsibility for benefits (as discussed later in this proposed rule) to mean that such a D–SNP would always satisfy the requirement of being a FIDE SNP or HIDE SNP. We believe that this proposed definition identifies the minimum requirements for an MA plan to be a D–SNP under section 1859 of the Act as amended by the Bipartisan Budget Act of 2018, as well as clarifies the applicability of the separate regulatory provisions that establish these minimum standards. We solicit comment whether our proposed definition meets these goals or should be revised to include other regulatory provisions that establish requirements for D–SNPs.

We believe it is important to clarify through this rulemaking the meaning of the requirement in section 1859(f)(3)(D) of the Act, which is currently codified at § 422.107(b), that the MA organization have responsibility under the contract for providing benefits or

[7] Verdier, J, Kruse, A., Sweetland Lester, R., Philip, A.M., & Chelminsky, D. (2016, November). ''State Contracting with Medicare Advantage Dual Eligible Special Needs Plans: Issues and Options.'' Retrieved from *http://www.integratedcareresourcecenter.com/PDFs/ICRC_DSNP_Issues__Options.pdf.*

arranging for benefits to be provided for individuals entitled to Medicaid. We have not interpreted the meaning of this statutory language, ''arranging for benefits,'' in previous rulemaking or in subregulatory guidance. We propose to interpret ''arranging for benefits'' as requiring a D–SNP, at a minimum, to coordinate the delivery of Medicare and Medicaid benefits. We propose to relocate this requirement to our proposed D–SNP definition. While our interpretation is consistent with the new statutory integration standards, this clarification is based on requirements for D–SNPs that existed prior to the enactment of the Bipartisan Budget Act of 2018 that we believe should be strengthened. We believe coordination would encompass a wide range of activities that a D–SNP may engage in for their dual eligible members. For example, if a D–SNP identifies through an enrollee's health risk assessment and/or individualized care plan, as required by § 422.101(f), functional limitations or mental health needs, the D–SNP would verify the enrollee's eligibility for LTSS and/or behavioral health services under Medicaid; determine how the enrollee receives such services (through FFS Medicaid or through another Medicaid managed care product); and make arrangements with the applicable Medicaid program (state Medicaid agency or managed care plan) for the provision of such services by the appropriate payer and/or provider. We recognize that not all of a D–SNP's membership will be eligible for the full complement of Medicaid services, particularly those who are partial-benefit dual eligible individuals whose Medicaid eligibility is limited to payment of their Medicare premiums, and if applicable, deductibles and cost-sharing.[8] However, for all enrollees who are eligible for Medicaid services, the D–SNP must fulfill its statutory responsibility to arrange for the provision of Medicaid benefits by facilitating a beneficiary's meaningful access to such benefits. We believe it would be insufficient for a D–SNP to limit its coordination activity simply to telling a beneficiary to call or write their Medicaid managed care plan or state agency without giving specific contact information, giving specific coaching on the roles of the Medicaid program (that is, the state agency or Medicaid managed care plan versus the D–SNP), and offering additional support if needed. We solicit comment on whether our proposed definition should be more prescriptive in identifying which plan activities constitute coordination or whether it should remain broadly defined as proposed.

We propose revising the definition of fully integrated dual eligible special needs plan at § 422.2 to align with the proposed definition of a D–SNP and to codify current policy. Specifically, we propose the following:

- Striking the reference to a ''CMS approved MA–PD'' plan in the current FIDE SNP definition and paragraph (1), which refers to the individuals eligible for enrollment in a FIDE SNP, because those provisions duplicate elements of the new proposed definition of a D–SNP at § 422.2;
- Replacing the reference to ''dual eligible beneficiaries'' with ''dual eligible individuals'' in newly redesignated paragraph (1) to align with the terminology used in section 1935(c) of the Act;
- Adding to newly redesignated paragraph (2) that a FIDE SNP's capitated contract with a state Medicaid agency may include specified behavioral health services, as well as replacing the term ''long-term care'' benefits with ''long-term services and supports'' to better describe the range of such services FIDE SNPs cover in capitated contracts with states. We also propose codifying in paragraph (2) the current policy that the FIDE SNP's capitated contract with the state provide coverage of nursing facility services for at least 180 days during the plan year;[9]
- Striking references to coordination of covered Medicare and Medicaid ''health and long-term care'' and referring more broadly to Medicare and Medicaid services in in newly redesignated paragraph (3); and
- Replacing the reference to ''member'' materials with ''beneficiary communication materials,'' consistent with the definition of ''communication materials'' at § 422.2260.

We propose to codify a definition of highly integrated dual eligible special needs plan (HIDE SNP) at § 422.2. Under the proposed definition, a HIDE SNP would be a type of D–SNP offered by an MA organization that has—or whose parent organization or another entity that is owned and controlled by its parent organization has—a capitated contract with the Medicaid agency in the state in which the D–SNP operates that includes coverage of LTSS, behavioral health services, or both, consistent with state policy.

We note that all the requirements of a D–SNP would also apply to a HIDE SNP, such as the obligation to provide, as applicable, and coordinate Medicare and Medicaid benefits. In contrast to a FIDE SNP, a D–SNP could satisfy the requirements of a HIDE SNP if its parent organization offered a companion Medicaid product that covered only LTSS or behavioral health services, or both, under a capitated contract. Because a FIDE SNP covers comprehensive Medicaid benefits including LTSS and behavioral health services, any FIDE SNP would also be a HIDE SNP, but not all HIDE SNPs would qualify to be FIDE SNPs. In defining a HIDE SNP, we chose to adopt the phrase ''consistent with state policy'' to align with the FIDE SNP definition. We interpret this phrase, both for FIDE SNPs and HIDE SNPs, as an important acknowledgement of variation in how states elect to provide coverage of LTSS or behavioral health services under their capitated contracts with D–SNPs and Medicaid managed care plans (for example, MCOs in the case of FIDE SNPs, and MCOs, PIHPs, and PAHPs in the case of HIDE SNPs). For example, one state may include all Medicaid behavioral health services in its capitated contracts, while another state may carve out a particular service from its capitated contracts with a Medicaid managed care plan covering behavioral health services. We interpret the phrase ''consistent with state policy'' as allowing CMS to permit certain carve-outs where consistent with or necessary to accommodate state policy, except for where specifically prohibited (such as for nursing facility services in the FIDE SNP definition). As such, among the states that have capitated contracts with D–SNPs or the D–SNPs' parent organizations, CMS can still determine that D–SNPs meet the FIDE SNP or HIDE SNP definition despite these types of variations allowed under this proposal. We solicit comment on this proposed definition, including on whether additional requirements for HIDE SNPs should be addressed in the definition.

We also propose to establish at § 422.2 a definition for the term aligned

[8] Partial-benefit dual eligible programs are commonly referred to collectively as the ''Medicare Savings Program'' (MSP). The MSP includes 4 eligibility groups: Qualified Medicare Beneficiary Program without other Medicaid (QMB Only) for whom Medicaid pays their Medicare Part A premiums, if any, Medicare Part B premiums, and to the extent consistent with the Medicaid State plan, Medicare Part A and B deductibles, coinsurance and copays for Medicare services provided by Medicare providers; Specified Low-Income Medicare Beneficiary Program without other Medicaid (SLMB Only) and Qualifying Individual (QI) Program for whom Medicaid pays the Part B premiums; Qualified Disabled and Working Individual (QDWI) Program for whom Medicaid pays the Part A premiums.

[9] Following the April 2, 2012 issuance of the ''Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter,'' Chapter 16b of the Medicare Managed Care Manual was revised to include this policy.

enrollment, as many of the other D–SNP proposals in this proposed rule are based on this concept. Under our proposal, aligned enrollment occurs when a full-benefit dual eligible individual is a member of a D–SNP and receives coverage of Medicaid benefits from the D–SNP or from a Medicaid managed care organization, as defined in section 1903(m) of the Act, that is: (1) The same organization as the MA organization offering the D–SNP; (2) its parent organization; or (3) another entity that is owned and controlled by the D–SNP's parent organization. Aligned enrollment, as we propose to define it, would not arise where the MA organization or its parent organization has a contract with the applicable state to offer a prepaid inpatient health plan (PIHP) or prepaid ambulatory health plan (PAHP) in the state's Medicaid program. Unlike a Medicaid MCO, these other Medicaid managed care plans cover only specific and non-comprehensive set of services. In the event that it is the policy of the state Medicaid agency to limit a D–SNP's membership to individuals with aligned enrollment, we would describe this practice as ''exclusively aligned enrollment,'' which is embedded in the definition of ''aligned enrollment.'' For example, some states limit D–SNP enrollment to full-benefit dual eligible individuals who also choose to receive Medicaid benefits through the D–SNP or a Medicaid MCO operated by the same entity (that is, by the MA organization) or by the MA organization's parent organization. Such a limitation would be included in the state Medicaid agency contract with the D–SNP. Exclusively aligned enrollment is relevant to how we propose to apply the integrated grievance and appeals requirements described in section II.A.2.b. of this proposed rule. We solicit comment on how we propose to define aligned enrollment given its relevance to the category of D–SNPs to which the integrated grievance and appeals procedures apply. We also solicit comment on whether we should consider other types of Medicaid managed care arrangements beyond companion Medicaid MCOs, as defined in section 1903(m) of the Act and codified at § 438.2, operated by a HIDE SNP's parent organization.

Finally, we propose in our definition of a D–SNP at § 422.2 to codify that an MA organization seeking to offer a D–SNP must satisfy any one (or more) of the three integration requirements in section 1859(f)(3)(D)(i) of the Act. We note that the statutory language requires that plans meet one or more statutorily identified integration requirements to the extent permitted under state law. We interpret this phrase as acknowledging and respecting the flexibility provided to states under the Medicaid program while imposing on D–SNPs integration requirements that Congress has deemed necessary. In approximately 20 states, state law does not permit enrollment of dual eligible individuals in managed care for Medicaid services, which would effectively preclude a D–SNP in such a state from being a HIDE SNP (paragraph 2) or FIDE SNP (paragraph 3). Similarly, in other states, certain Medicaid benefits, such as LTSS and behavioral health services, are carved out of Medicaid managed care, which could similarly preclude a D–SNP from meeting paragraphs (2) or (3) of our proposed definition of a D–SNP. As we discuss in the context of our definitions of a FIDE SNP and HIDE SNP, a carve-out by the state of a minimal scope of services is permissible so long as comprehensive services are covered under the capitated Medicaid contract. For these reasons, we propose to interpret this statutory provision in a way that provides multiple avenues for a MA plan to qualify as a D–SNP. However, we considered other interpretations of this particular provision. For example, we considered whether this phrase should mean that in states that have Medicaid managed care programs for dual eligible individuals, all MA organizations seeking to offer a D–SNP could do so only if they were under contract with the state to offer a companion Medicaid managed care plan in that state, on the grounds that such an opportunity is permitted under state law. We solicit comments on our proposed interpretation as well as alternatives. We also request comment on whether and how our proposed definition could or should be revised consistent with the interpretation we take of the statute.

These proposed definitions serve to describe different types of D–SNPs based on the degree to which they integrate Medicaid benefits at the plan level. FIDE SNPs that limit enrollment to full-benefit dual eligible individuals and require (or have) exclusively aligned enrollment across Medicare and Medicaid constitute the most extensive level of integration, with the greatest potential for holistic and person-centered care coordination, integrated appeals and grievances, comprehensive beneficiary communication materials, and quality improvement. HIDE SNPs with exclusively aligned enrollment are plans that share much of this potential but integrate a narrower set of Medicaid benefits than FIDE SNPs. We believe that an entity can only truly hold ''clinical and financial responsibility'' for the provision of Medicare and Medicaid benefits, as described at section 1859(f)(8)(D)(i)(III) of the Act, in the scenarios of exclusively aligned enrollment. Therefore, the plans that meet this criterion would be FIDE SNPs and HIDE SNPs that have exclusively aligned enrollment, as these terms are defined under our proposal. By virtue of these exclusively aligned plans' status as a FIDE SNP or HIDE SNP, they would also satisfy the integration requirement at section 1859(f)(8)(D)(i)(II) of the Act, which we codified in paragraphs (2) and (3) of the definition of a D–SNP at § 422.2.

FIDE SNPs and HIDE SNPs where aligned enrollment is possible—but not required—under the state contract with the D–SNP and the state's administration of its Medicaid managed care program would constitute another form of integration, albeit to a lesser degree. In such a D–SNP, it is likely that some share of the D–SNP's enrollment is aligned enrollment but not exclusively aligned enrollment. Some dual eligible individuals enrolled in that plan may: (1) Enroll in a Medicaid managed care plan operated by a different parent organization; or (2) receive their Medicaid benefits through Medicaid fee-for-service. These other choices may be a result of individual choice even when a Medicaid managed care plan offered by the same entity (or parent organization) as the MA D–SNP is available or may be the result of the applicable state's decisions in administering its Medicaid program.

Under section 1859(f)(8)(D)(i) of the Act, those D–SNPs that are neither FIDE SNPs nor HIDE SNPs must meet an additional state Medicaid contracting requirement beginning in 2021. Our proposed definition of a D–SNP addresses this in paragraph (1), cross-referencing the proposed new requirement in paragraph (d) of § 422.107. This new requirement, which involves the provision of notice when an individual who belongs to a group of high-risk dual eligible individuals has a hospital and skilled nursing facility admission, is discussed in section II.A.2.b.(2) of the proposed rule in greater detail. We solicit comments on this proposal and, in particular, on alternative approaches to classifying D–SNPs consistent with requirements of section 1859(f)(8)(D)(i) of the Act.

(2) Dual Eligible Special Needs Plans and Contracts With States (§ 422.107)

In § 422.107, we propose changes to more clearly articulate the requirements of the contract between the D–SNP and the state Medicaid agency, while also incorporating the changes required by the Bipartisan Budget Act of 2018. In summary, we propose to make the following changes:

- Delete language in paragraph (b) that is extraneous and duplicative of the proposed definition of a D–SNP in § 422.2;
- Make clarifying edits in paragraphs (c)(1) through (c)(3), which govern the minimum requirements of the contract between the D–SNP and the state Medicaid agency;
- Redesignate paragraph (d) as paragraph (e), which relates to compliance dates; and
- Establish a revised paragraph (d) that describes the new minimum contracting requirement under the Bipartisan Budget Act of 2018 that the newly designated paragraph (e)(2) would make effective January 1, 2021.

Section 50311(b) of the Bipartisan Budget Act of 2018 amended section 1859(f) of the Act by creating a new paragraph (8)(D)(i)(I) to require that the Secretary establish additional requirements for D–SNPs' contracts with state Medicaid agencies. We address in our preamble discussion about our proposed definition of D–SNP how this provision requires a D–SNP to have a state Medicaid agency contract that includes additional coordination requirements (subsection (f)(8)(D)(i)(I) of the Act); be a FIDE SNP or HIDE SNP (subsection (f)(8)(D)(i)(II) of the Act); or have exclusively aligned enrollment and have its parent organization accept full clinical and financial responsibility for all Medicare and Medicaid covered services (subsection (f)(8)(D)(i)(III) of the Act), depending on the state's election.

We are proposing to implement subsection (f)(8)(D)(i)(I) of the Act itself by establishing at § 422.107(d) that any D–SNP that is not a FIDE SNP or HIDE SNP is subject to an additional contracting requirement. Under this proposed new contract requirement, the D–SNP would be required to notify the state Medicaid agency, or individuals or entities designated by the state Medicaid agency, of hospital and skilled nursing facility (SNF) admissions for at least one group of high-risk full-benefit dual eligible individuals, as determined by the state Medicaid agency. Our proposal would also permit the D–SNP to authorize another entity or entities (such as a D–SNP's network providers) to notify the state Medicaid agency and/or individuals or entities designated by the state Medicaid agency on its behalf, with the understanding that the D–SNP ultimately would retain responsibility for complying with this requirement. Our intent in proposing this notification requirement is to promote the integration of Medicare and Medicaid benefits by establishing a minimum contracting requirement that has the effect of increasing D–SNPs' care coordination activity around care transitions. In such care transitions, there is a clear need to share information among parties concerned with the beneficiary's care and there is a risk of potential harm to the beneficiary when effective communication and coordination do not occur. In our experience, there are known gaps when a beneficiary migrates from one setting where services are covered under Medicare, such as an inpatient or SNF stays, to another setting where services such as LTSS, including home and community based services (HCBS), that are covered under Medicaid.[10] This proposed provision is intended to promote successful transitions of care into a setting of the beneficiary's choice, and increase coordination among those involved in furnishing and paying for primary care, acute care, LTSS, and behavioral health services. The proposed requirement for notification is just one facet of successful, holistic care transitions, but we believe it is an essential catalyst for the process.

In permitting a state Medicaid agency to specify which subpopulations of high-risk full-benefit dual eligible individuals the D–SNP must focus on through this effort, we are seeking to give states flexibility to begin on the path toward greater integration on a smaller scale and, in collaboration with the D–SNPs in their markets, test different approaches. As processes and infrastructure mature, a state Medicaid agency may choose through its contracts with D–SNPs to scale up this notification to include additional data, additional subpopulations of full-benefit dual eligible individuals, or both. High-risk beneficiaries could include those who are receiving HCBS or participating in a Medicaid health home program in accordance with section 1945 of the Act. Alternatively, or in addition, the state Medicaid agency could use claims or encounter data to target particular groups, such as those who have a history of hospital readmissions or who are high utilizers of acute care services, LTSS, or behavioral health services. Under this proposal, we would give the state Medicaid agency broad latitude to establish notification procedures and protocols, including the recipients of the admission notifications, timeframes by which a D–SNP must furnish this information directly or indirectly, and how such notification would occur. We are proposing to defer to state Medicaid agencies on the manner in which notification occurs, that is, whether it involves an automated or manual process. For example, in markets where there is existing infrastructure to leverage, such as a state health information exchange, a state may elect an approach that requires data sharing across a common platform using industry standards, including those adopted by the Office of the National Coordinator for Health IT in accordance with 45 CFR part 170, subpart B. Regardless of process, the expectation is that notifications occur timely in order to ensure prompt care coordination and effective care transitions. To that end, we strongly encourage states to use the most efficient notification mechanisms available, which may include the state's health information exchange. However, we appreciate that not every state is similarly positioned and, therefore, if a state elected to implement this requirement on a smaller scale, targeting a small subset of beneficiaries, a solution that does not initially require automation may be more appropriate and pragmatic. We support state Medicaid agencies in their efforts to adopt the policies and procedures for this notification requirement that work best for them and D–SNPs participating in their markets. Regardless of what approach a state chooses to take under this proposal, our aim is to have actionable information that enables providers and payers to facilitate seamless care transitions for high-risk populations, that is, those full-benefit dual eligible individuals who are among the most ill and medically complex or who are most likely to benefit from effective interventions (such as through the provision of LTSS and behavioral health services) that enable them to live independently in the setting of their choice and in a way that values their own needs and preferences.

We believe that our proposal to establish a notification requirement for D–SNPs for high-risk individuals'

[10] ''Improving Care Transitions,'' Health Affairs Health Policy Brief, September 13, 2012. DOI: 10.1377/hpb20120913.327236. Retrieved from *https://www.healthaffairs.org/do/10.1377/hpb20120913.327236/full/;* and Segal, M., Rollins, E., Hodges, K., and Roozeboom, M. ''Medicare-Medicaid Eligible Beneficiaries and Potentially Avoidable Hospitalizations.'' *Medicare & Medicaid Research Review,* 2014: 4 (1), p. E1–E10. Retrieved from *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4053188/pdf/mmrr2014-004-01-b01.pdf.*

hospital and skilled nursing facility admissions is consistent with the criteria we used to evaluate various options for the minimum contracting requirements. We considered whether a proposal would—

- Meaningfully improve care coordination and care transitions, thereby improving health outcomes for dually eligible beneficiaries;
- Minimize burden on plans and states relative to the improvements in care coordination and transitions;
- Provide flexibility to state Medicaid agencies;
- Enable CMS to assess compliance with minimal burden on CMS, plans, and providers; and
- Be consistent with the statutory amendments made by the Bipartisan Budget Act of 2018.

We solicit comment on whether our proposal satisfies these criteria to a greater extent than the more prescriptive or alternative proposals we considered as described in further detail in this section of this proposed rule; whether our reasoning for why our proposal is preferable to the more prescriptive or alternative proposals is sound; whether there are other minimum contacting requirements that we did not consider that are superior to our proposal; and whether our proposal provides sufficient incentives for plans and states to pursue greater levels of integration. For example, we considered the following:

- We considered proposing that notice requirements apply for all full-benefit dual eligible individuals' hospital and SNF admissions. We believe our proposal is preferable because it limits the administrative burdens for states and MA organizations and focuses efforts on high-risk beneficiaries for whom there is likely to be some Medicaid care coordination infrastructure.
- We considered proposing a minimum size for the state-selected high-risk population. In contrast, our proposal for new § 422.107(d) gives state Medicaid agencies the discretion to decide what it means that a group of beneficiaries is at high risk and how large or small the group(s) may be.
- We considered requiring a notification for every emergency department visit, as mentioned in section 1859(f)(8)(D)(i)(I) of the Act. We believe our proposal is preferable because it focuses on hospital and SNF admissions where CMS believes there is the greatest opportunity to target interventions and improve outcomes, and during which there is more time to initiate discharge planning than during an emergency department visit. However, we note that a state Medicaid agency could choose to require a notification for full-benefit dual eligible individuals who are high utilizers of emergency departments, where there may be opportunities to address barriers to accessing primary care and unmet health care needs.
- We considered proposing that the notification occur not later than 48 hours after the D–SNP learns of the admission or discharge. We opted instead to defer to the state Medicaid agency on such matters. We believe that states may choose to use this information for their own purposes, including program oversight; alternatively, or in addition, a state Medicaid agency may opt to require a direct notification between the D–SNP and Medicaid managed care organization (MCO) or a specified Medicaid provider to allow for the timeliest action following a care transition or other significant event.
- We considered focusing on better coordination of individual health needs assessments and mechanisms to reduce assessment burden for enrollees. We continue to hear of scenarios where a D–SNP enrollee is assessed separately by the D–SNP and then again by their Medicaid MCO, even though there may be a high degree of overlap in what each organization is assessing and ultimately what each organization is asking of the enrollee. Because we are unclear on the scope of the problem, we solicit comment on how pervasive this issue is and the extent of overlap in the assessment instruments and degree of burden on providers and beneficiaries. We welcome feedback for our consideration in the final rule, specifically on the extent to which the requirements that we propose do not accomplish enough or should be modified to address this issue. For example, we seek comment on whether a coordination obligation for D–SNPs should be adopted that could require, for example, each D–SNP to take affirmative steps to schedule its assessments at the same time as similar outreach is conducted by the Medicaid managed care plan, to use a combined or aligned assessment instrument, or take other steps that would minimize the burden on enrollees or providers.
- We considered requiring D–SNPs to identify any enrollees who are in need of LTSS and behavioral health services and transmitting such information to the state Medicaid agency. However, D–SNPs are already required, at § 422.101(f), to develop individualized care plans and perform health risk assessments that identify the physical, psychosocial, and functional needs of each SNP enrollee. We do not wish to duplicate an existing requirement, but to the extent the current regulation text is insufficient to accomplish this or additional regulatory standards for identifying and sharing information are necessary, we welcome comment on that topic.
- We considered requiring D–SNPs to train plan staff and their network providers on the availability of LTSS and behavioral health services covered by Medicaid. While we believe that such awareness, understanding, and training are vitally important to delivering appropriate care to full-benefit dual eligible individuals, we also believe that it is an intrinsic administrative function of a D–SNP in fulfilling its responsibility to coordinate the delivery of Medicare and Medicaid benefits and therefore potentially duplicative of existing requirements, including the requirement to train plan staff and network providers on the D–SNP model of care.
- We considered requiring D–SNPs to solicit state input on the plan's model of care (which is currently required and submitted to CMS pursuant to § 422.101(f)), health risk assessment instrument, and beneficiary communication materials. However, we were disinclined to impose such a requirement on D–SNPs that do not have exclusively aligned enrollment. Further, in states without capitated arrangements with D–SNPs for the provision of Medicaid services, Medicaid agencies may not see a role for themselves in reviewing such documents, and we did not want such a requirement to create additional burden for states. State Medicaid Agencies, however, can choose to require that a D–SNP provide such documents for state input through their contracts with D–SNPs. We seek comment on whether our assumptions about state burden are correct and whether there are compelling reasons why additional contracting requirements in this area may be necessary.
- Finally, we considered the merits of requiring D–SNPs to share data with state Medicaid agencies or entities designated by State Medicaid Agencies that would benefit the coordination of Medicare and Medicaid items and services, as described in section 1859(f)(8)(D)(i)(I) of the Act, as an example for implementing that provision. However, we ultimately decided against proposing such a requirement here so we can further assess the operational and technical hurdles and costs for both state Medicaid agencies and D–SNPs. Instead,

we are proposing to focus initially on establishing the notification requirement for hospital and SNF admissions, which we believe will lead to more immediate improvements in the care transitions process. However, we solicit comment on whether there should be additional regulatory requirements around data sharing.

We seek feedback on our notification proposal at § 422.107(d), including the ways that State Medicaid Agencies and plans would fulfill this requirement, and the additional contracting requirements we considered, as summarized in this section.

In addition to the new requirement for contracts between the State and MA organization at proposed § 422.107(d) for D–SNPs that are not FIDE SNPs or HIDE SNPs, we are proposing to include additional specifications in the regulations governing D–SNP contracts with State Medicaid Agencies at § 422.107 by amending paragraph (b) and several provisions in paragraph (c). We do not believe that these specifications materially alter these agreements; however, we are proposing them in response to questions raised since the State Medicaid agency contracting requirements were promulgated in the September 2008 interim final rule (73 FR 54226). We also believe that these changes align with the integration requirements for D–SNPs in the Bipartisan Budget Act of 2018.

We are proposing to modify the general rule for contracts with D–SNPs at § 422.107(b) to strike ''The MA organization retains responsibility under the contract for providing benefits, or arranging for benefits to be provided, for individuals entitled to receive medical assistance under Title XIX. Such benefits may include long-term care services consistent with state policy.'' We believe that these sentences would no longer be necessary to describe the mandatory content of the contract. Our proposed definition at § 422.2 of ''D–SNP'' requires the plan to provide, as applicable, and coordinate the delivery of Medicare and Medicaid services; we believe this is sufficient for D–SNPs to be aware of the requirement and for CMS to enforce it.

We propose to revise the contracting requirement at § 422.107(c)(1), which currently requires the contract to document the MA organization's responsibility, including financial obligations, to provide or arrange for Medicaid benefits to specify instead that the contract must document the MA organization's responsibility to provide, as applicable, and coordinate the delivery of Medicaid benefits, including LTSS and behavioral health services, for individuals who are eligible for such services. This proposed revision would clarify that in some cases, the D–SNP may cover (that is, provide directly or pay health care providers for providing) Medicaid benefits under a capitated contract with the State Medicaid agency, but in all cases, it must coordinate the delivery of Medicaid benefits. In addition to being codified in our proposed revisions to § 422.107(c)(1), this is consistent with our proposed definition of ''dual eligible special needs plan,'' which indicates that each D–SNP ''coordinates the delivery of Medicare and Medicaid services.'' Current regulations use the phrase ''providing benefits, or arranging for benefits to be provided'' but do not describe what it means for D–SNPs to provide or arrange for Medicaid benefits; we believe this proposed amendment to impose an affirmative duty to provide benefits, as applicable, and otherwise coordinate the delivery of benefits clarifies that D–SNPs must play an active role in helping beneficiaries access such services as necessary. We further believe that ''coordination'' more aptly describes the activity in which D–SNPs are engaged with respect to a beneficiary's Medicaid benefits. We solicit comment on whether our proposed amendments to this section fully communicate what we intend to require of D–SNPs or whether there are additional revisions we ought to consider to express our intent more clearly for D–SNPs, State Medicaid Agencies, and other stakeholders.

In § 422.107(c)(2), we propose to revise the current requirement that the contract between the D–SNP and the State Medicaid Agency document the categories of dual eligible individuals who are eligible to enroll in the D–SNP. This provision currently requires the contract to specify whether the D–SNP can enroll categories of partial-benefit dual eligible individuals or whether enrollment is limited to full-benefit dual eligible individuals. We are proposing to revise this requirement to specify not only the categories of eligibility but also any additional criteria of eligibility to account for such conditions of eligibility under Medicaid as nursing home level of care and age. These criteria could also include a requirement for D–SNP enrollees to enroll in a companion Medicaid plan to receive their Medicaid services.

Finally, at § 422.107(c)(3), we propose that the contract between the D–SNP and the State Medicaid Agency document the Medicaid services the D–SNP is responsible for covering in accordance with a capitated contract with the D–SNP directly or through a risk contract, defined at § 438.2, with the companion Medicaid managed care organization operated by the D–SNP's parent organization. We believe that this change, if finalized as proposed, would reduce burden on D–SNPs to identify and document in the contract every Medicaid-covered service. D–SNPs often submit to CMS a list of all Medicaid services in their State Medicaid Agency contracts, even those for which the D–SNP is not under a capitated contract and for which the D–SNP bears no risk. Even with this change, we continue to expect D–SNPs, for purposes of coordinating their enrollees' Medicaid benefits as required in the proposed definition of a D–SNP in § 422.2, to know and understand all services covered in each state's approved state plan, including any services that may be carved out and covered separately from the D–SNP. This clarifying change would enable us to identify the particular Medicaid services that are covered under a capitated contract for FIDE SNPs and HIDE SNPs, and we seek comment on whether the regulatory change fully communicates what we wish to require. We intend to issue sub-regulatory guidance to address any changes made under this rulemaking that impact D–SNPs contracts with State Medicaid Agencies.

(3) Conforming and Technical Changes (§§ 422.60(g), 422.102(e), 422.107(b), and 422.111(b)(2)(iii))

We are also proposing to make conforming changes to several sections of Part 422 that address D–SNPs by adopting consistent terminology with respect to dual eligible individuals and creating cross-references to the newly proposed definitions. First, at § 422.60(g), which addresses CMS authority to implement passive enrollment, we propose to use the term ''highly integrated dual eligible special needs plan'' in place of text referring to D–SNPs that meet a high level of integration. This is consistent with our new proposed definition in § 422.2. This technical change would not materially change the plan types that are eligible for passive enrollment; the existing rule simply refers to them as D–SNPs that meet a high standard of integration under the supplemental benefit authority at § 422.102(e). Second, we also propose clarifying at § 422.102(e) that not only HIDE SNPs meeting minimum quality and performance standards are eligible to offer supplemental benefits, but FIDE SNPs that similarly meet minimum quality and performance standards may do so as well. While this amendment does not

change what has occurred in practice, we believe it clarifies the types of plans that are eligible to offer enhanced supplemental benefits. Third, in the general rule at § 422.107(b), we are proposing to substitute a ''special needs plan serving beneficiaries eligible for both Medicare and Medicaid (dual-eligible)'' with ''dual eligible special needs plan.'' Already explicit in the proposed definition of a D–SNP is that such plans exclusively serve individuals who are eligible for Medicaid under Title XIX of the Act, and we believe that the language in the current regulations is extraneous. Finally, at § 422.111(b)(2)(iii), which requires D–SNPs to provide written information to dual eligible enrollees about their eligibility for cost-sharing protections and Medicaid benefits, we propose to use the term ''dual eligible special needs plan'' consistent with the proposed definition.

(4) Eligibility of Partial-Benefit Dual Eligible Individuals for Dual Eligible Special Needs Plans

We considered proposing limits on the enrollment of partial-benefit dual eligible individuals in D–SNPs, since there are no Medicaid services that the D–SNP is integrating or coordinating on their behalf. We continue to question the benefit that partial-benefit dual eligible individuals derive from their enrollment in a D–SNP relative to the challenges associated with allowing such enrollment. For example, allowing D–SNPs to enroll both partial- and full-benefit dual eligible individuals significantly limits the ability of plans, CMS, and states to simplify beneficiary communications materials. We ultimately decided against proposing any such limits on enrollment at this time but continue to consider this issue. We invite comments on this topic.

(5) Suspension of Enrollment for Non-Compliance With D–SNP Integration Standards (§ 422.752)

Section 50311(b) of the Bipartisan Budget Act of 2018 amended section 1859(f) of the Act by creating a new paragraph (8)(D)(ii) to permit the Secretary, for plan years 2021 through 2025, to impose an intermediate sanction of stopping all new enrollment into a D–SNP if the Secretary determines that the D–SNP is failing to comply with the integration requirements set forth in section 1859(f)(8)(D)(i) of the Act. By establishing statutory requirements that established a minimum level of integration of D–SNPs in section 50311 of the Bipartisan Budget Act of 2018, we believe the goal was for all dual eligible beneficiaries enrolled in D–SNPs to receive a greater level of integration of Medicare and Medicaid benefits than is the case under current regulations. Because the Bipartisan Budget Act of 2018 limited the applicability of the Secretary's authority to impose an intermediate sanction on plans that do not comply with the integration requirements to plan years 2021 through 2025, we believe that the intent of this provision is to offer an alternative to outright contract or plan termination for D–SNPs that fail to meet the new integration requirements during the period of 2021 through 2025. We believe the enrollment sanction authority is a lesser penalty than a contract or plan termination to provide time for D–SNPs to transition to the new integration requirements without creating potentially significant disruption to current D–SNP enrollees as a result of outright termination. In addition to authorizing this lesser sanction, the statute requires a corrective action plan, which we believe strengthens our interpretation, as it illustrates a preference for ultimate compliance by D–SNPs with the integration requirements. As provided in section 1859(f)(8)(D)(i) of the Act, in the event that such a sanction is imposed, the plan must submit to the Secretary (at a time, and in a form and manner, specified by the Secretary) information describing how the plan will come into compliance with the integration requirements.

The statute authorizes this lesser sanction but does not require that it be used, leaving it to our discretion whether an enrollment sanction combined with a corrective action plan is sufficient to achieve the goals of the statute. We believe that it would be appropriate to impose the enrollment sanction for non-compliant D–SNPs before initiating any contract termination or other sanction or enforcement action. Therefore, we propose to amend § 422.752 by adding a new paragraph (d) that would require CMS to impose an enrollment suspension when CMS finds that the plan is non-compliant with the integration requirements during plan years 2021 through 2025, rather than initiating outright termination. While the statute grants the Secretary discretion to sanction plans that fail to meet the new integration requirements, starting in 2021, by stopping all new enrollment into such plans, our proposal would establish predictability for states, beneficiaries, and MA organizations by requiring its imposition for non-compliant plans in lieu of termination or other actions. However, we stress that we interpret this proposal as leaving discretion for CMS, if the D–SNP does not submit an acceptable corrective action plan or fails to abide by the correction action plan, to determine that contract termination or other action is still possible. In addition, in the event that any harm to enrollees is imminent, we retain authority to immediately terminate the contract. We also propose in § 422.752(d) that the suspension of enrollment would continue in effect until CMS is satisfied that the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur. The procedures, remedies, and appeal rights available to plans subject to intermediate sanctions provided in § 422.756 would apply to D–SNPs that are sanctioned under this new authority.

b. Unified Grievance and Appeals Procedures for Dual Eligible Special Needs Plans and Medicaid Managed Care Plans at the Plan Level (§§ 422.560–562, 422.566, 422.629–634, 438.210, 438.400, and 438.402)

Section 1859(f)(8)(B) of the Act, as added by the Bipartisan Budget Act of 2018, directs the Secretary to establish new procedures that unify, to the extent feasible, Medicare and Medicaid grievance and appeals procedures for D–SNPs. This new authority provides an important opportunity to address an area of longstanding misalignment between the Medicare and Medicaid programs. Medicare and Medicaid grievance and appeal processes have developed independently and operate entirely separately. Medicare's fee-for-service appeals processes (authorized primarily under section 1869 of the Act for Part A and B claims appeals), and MA's processes (authorized under sections 1852(f) and 1852(g) of the Act for grievance and appeal processes) are subject only to federal regulation and oversight as part of the federally-administered Medicare program. Medicaid grievances and appeals are authorized under sections 1902(a)(3) and 1902(a)(5) of the Act for Medicaid programs more generally and section 1932(b)(4) of the Act for Medicaid managed care plans. Unlike Medicare and MA, Medicaid appeals and grievance procedures are subject to both federal and state regulation and are primarily subject to state oversight and administration as part of a joint federal-state financed program. Medicare Part D grievances and appeals are authorized under sections 1860D–4(f) and (g) of the Act and are outside the scope of our authority to unify grievances and

appeals under new section 1859(f)(8)(B) of the Act; we note, however, that D–SNPs are all required to provide Part D prescription drug coverage pursuant to § 422.2.

Both the Medicare and Medicaid grievance and appeals systems include regulations establishing procedures for the fee-for-service programs as well as regulations governing managed care plans, including processes at the plan and post-plan levels for adjudicating appeals. Medicare rules are found at 42 CFR part 405 subpart I (general) and part 422 subpart M (Medicare Advantage); Medicaid rules are at 42 CFR part 431 subpart E (general) and part 438 subpart F (managed care). Regulations for the Medicare and Medicaid programs take broadly similar approaches to managed care appeals in that both programs establish a process for resolving a dispute at the plan level initially, followed by an opportunity for post-plan review. However, these appeals systems operate independently with sometimes subtle but important differences related to notices, adjudication timeframes, availability of benefits continuing while the appeal is pending, and levels of review. Similarly, regulations for the Medicare and Medicaid programs take different approaches with respect to some processes for grievances, including filing and adjudication timeframes and the availability of an expedited grievance process.

Although comparatively few beneficiaries file grievances or appeals,[11] these processes are vital safeguards to ensure that beneficiaries' concerns and needs are met promptly. Because of Medicare and Medicaid's misalignments in this area, beneficiaries who are dually eligible for Medicare and Medicaid can face a confusing array of choices when they seek to file a grievance or appeal. They may not know whether their complaint is tied to Medicare or Medicaid, and thus may not know where to direct their grievance. They may be uncertain if the item or service they seek is covered by Medicare, by Medicaid, or potentially by both programs, and thus may not know when or where to file an appeal following the denial of a service. The issue is particularly complicated for items and services such as home health and certain durable medical equipment that are sometimes covered by both programs but under different circumstances.

This confusion for beneficiaries and for those assisting them can result in costly and inefficient duplication of effort, as beneficiaries may file grievances and appeals under both programs when only one was necessary. Health plans and federal and state agencies may incur additional burdens and costs from having to administer parallel appeals systems. Finally, these misalignments may lead to unintended harms in the form of delayed or denied access to needed services as beneficiaries expend time and energy pursuing ultimately fruitless appeals in one program when they should have been pursuing them in the other.

We have made previous efforts to better align Medicare and Medicaid grievances and appeals for dual eligible individuals. The success of these prior efforts suggests to us that further alignment in this area is feasible. Under § 460.122, the Programs of All-inclusive Care for the Elderly (PACE) include an integrated appeals system that handles all initial appeals at the organization level. The Medicaid managed care May 2016 final rule (81 FR 27478) took several steps to bring Medicaid managed care grievance and appeals rules into closer alignment with both Medicare and the private insurance market. Notable changes for Medicaid managed care enrollees in that final rule included requiring one single level of plan review prior to the state fair hearing as well as aligning many timeframes for resolving grievances and appeals.

The operation of Medicare-Medicaid Plans (MMPs) in the CMS' Financial Alignment Initiative capitated model demonstrations has provided us with the most extensive experience integrating grievances and appeals for dually eligible enrollees in the managed care setting. MMPs are responsible for covering the full range of Medicare and Medicaid benefits and operating integrated grievance and appeals systems. We have developed these systems in collaboration with participating State Medicaid Agencies, using waiver authority under section 1115A of the Act and, in some cases, section 1115 of the Act. Development of these systems has required in-depth examination of various aspects of Medicare and Medicaid grievance and appeals rules to determine where misalignments exist and to decide how to resolve these misalignments in a way that is maximally protective of beneficiaries' rights. Our experience with MMPs suggests that, although implementing a new system can be challenging, once in operation integrated grievance and appeals systems can be simpler for beneficiaries to navigate than separate systems for Medicare and Medicaid.

Under the newly enacted amendments to section 1859(f)(8)(B) of the Act, the Secretary is required to establish, not later than April 2020 and for inclusion in contracts for D–SNPs for 2021 and subsequent years, procedures unifying grievances and appeals procedures consistent with several principles:

- Under paragraph (8)(B)(ii), the new unified procedures must include provisions that are most protective for the enrollee and, to the extent feasible as determined by the Secretary, are compatible with unified timeframes and consolidated access to external review. The statute requires that the procedures take into account differences under state Medicaid plans, and be easily navigable by enrollees.
- Additionally, under paragraph (8)(B)(iii), the integrated processes implemented are required to include a single written notice that includes all relevant grievance and appeal rights; a single pathway for resolution of covered items and services; notices written in plain English and available in languages and formats that are accessible to enrollees (including in non-English languages that are prevalent in the service area of the specialized MA plan); unified timelines for processes such as filing, acknowledging, and resolving the appeal or grievance; and requirements for plans to process, track, and resolve the grievances and appeals to ensure enrollees are notified timely of decisions and can track the status of their grievance or appeal.
- Finally, under paragraph (8)(B)(iv), new grievance and appeals procedures shall, with respect to all benefits under Medicare Parts A and B and Medicaid subject to appeal under such procedures, incorporate provisions under current law and implementing regulations that provide continuation of benefits pending appeal under Title XVIII and Title XIX. We address this statutory provision in section II.A.2.b.(7).

Using this statutory framework, we developed the following goals to guide development of proposals to implement the unified grievance and appeals provisions:

- Adopt provisions that are most protective of the enrollee;
- Reduce burden on beneficiaries (and those assisting them), plans, states, and providers; and

[11] For example, in 2016, Medicare Part C plans reported 2.93 complaints (grievances) per 1,000 enrollees per month and 19.3 reconsideration requests (appeals) per 1,000 enrollees per month. See Analysis of Calendar Year 2016 Medicare Part C Reporting Requirements Data, available at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartCDDataValidation.html*.

• Maintain state flexibility and minimize disruption by building on existing rules and policies.

These policy goals also reflect our belief that timely, efficient, accessible, and well-functioning grievance and appeals systems are critical to ensuring that beneficiaries have access to needed items and services. Such systems are especially vital for dually eligible beneficiaries who typically lack financial resources that might enable other beneficiaries to pay out-of-pocket for needed items or services while a dispute is pending. We welcome comments regarding these policy goals and the extent to which the proposed regulations are consistent with them.

Our policy goal of minimizing disruption is informed by statutory language directing the Secretary to establish unified provisions to the extent feasible (section 1859(f)(8)(B)(i) of the Act). Consistent with this statutory standard, we are primarily proposing incremental changes that are currently feasible, conform to other current law, and build upon existing systems. As we gain further experience with unified grievances and appeals, we may consider additional changes in the future, consistent with our authority.

Our proposals under this notice of proposed rulemaking can be divided into two substantively different types in addition to technical amendments proposed. We propose to incorporate these changes into and conform existing regulations in parts 422 and 438. First, we are proposing to establish requirements for all D–SNPs, relative to the role they play in assisting full-benefit dual eligible individuals, to assist with Medicaid-related coverage issues and grievances (§ 422.562(a)). Second, we are also proposing new requirements in accordance with section 1859(f)(8)(B) of the Act to create integrated grievance and appeals systems for a limited subset of D–SNPs (''applicable integrated plans''), identified using terms and concepts we propose to define in amendments to § 422.561, with the integrated processes established by proposed new regulations (§§ 422.629–422.634). Finally, we propose a number of changes of a technical and conforming nature to existing provisions in parts 422 and 438 (§§ 422.560, 422.562, 422.566, 438.210, 438.400, and 438.402).

Section 1859(f)(8)(B)(i) of the Act requires the Secretary to establish unified grievance and appeals procedures for D–SNPs not later than April 2020, and section 1859(f)(8)(C) of the Act requires the use of these unified procedures in D–SNP contracts for 2021 and subsequent years. The statute does not, however, explicitly rule out the possibility of implementing such unified processes prior to 2021. We interpret the statute as permitting a state to adopt unified grievance and appeals processes for integrated D–SNPs and Medicaid plans in that state consistent with our final regulations on this topic starting as soon as the regulations establishing such procedures are final. Such a state could require establishment of unified appeals and grievance procedures consistent with CMS' regulations in its Medicaid agency contract required under § 422.107. We solicit comments on this interpretation of the statutory implementation date requirements and our proposal to make unified procedures available to states in this way before 2021.

(1) Assisting With Medicaid Coverage Issues and Grievances (§ 422.562(a)(5))

As an incremental step towards improving all D–SNP enrollees' experiences with accessing Medicaid benefits, and pursuing grievances and appeals, we propose new regulation text to require all D–SNPs to assist beneficiaries with Medicaid coverage issues and grievances, including authorizations for or appeals related to Medicaid-related services at § 422.562 by adding a new paragraph (a)(5). These new requirements are consistent with our existing guidance and expectations for D–SNPs, but we are proposing regulations to define their scope and set mandatory standards to which we can hold D–SNPs accountable. Consistent with the statutory requirement at section 1859(f)(3)(D) of the Act that D–SNPs arrange for their enrollee's Medicaid benefits, we believe that all D–SNPs should assist enrollees with resolving Medicaid coverage problems, including assistance with filing grievances, requesting coverage, and requesting appeals. Such assistance is consistent with the standard we are proposing as part of the definition of a D–SNP in section II.A.2.a of this proposed rule, which states that all D–SNPs provide a minimum level of coordination across Medicare and Medicaid. Under our proposal, D–SNPs have a responsibility to coordinate the delivery of Medicaid services for enrollees whether or not the D–SNP itself contracts with the state to provide Medicaid services. We clarify here that the requirements at 422.562(a)(5) are additional requirements for D–SNPs, specifically related to assisting with access to benefits, appeals and grievances. At § 422.562(a)(5), we propose to supplement the obligation to provide, as applicable, and coordinate Medicaid benefits by adding a requirement that when a D–SNP receives an enrollee's request for services, appeal, or grievance related to Medicaid-covered services (regardless of whether such coverage is in Medicaid fee-for-service or a Medicaid managed care plan, such as a Medicaid MCO, PIHP, or PAHP as defined in § 438.2), the D–SNP must provide a certain level of assistance to the enrollee. This proposal, which we hope would result in a more seamless process for enrollees in accessing Medicaid benefits and pursuing grievance and appeals for D–SNP enrollees, complements how we believe section 1859(8)(f)(B) of the Act directs us to unify D–SNP and Medicaid appeal and grievance procedures to the extent feasible.

In new paragraph (a)(5)(i), we propose to describe the types of assistance we would require all D–SNPs to provide to their enrollees regarding Medicaid-related coverage issues and grievances, including authorization of services, and appeals. We propose in paragraph (a)(5)(i) to include assistance for all D–SNP enrollees, regardless of the type of Medicaid coverage in which they are enrolled. While we specifically list Medicaid fee-for-service and Medicaid managed care plans, it is not our intention to exclude any type of Medicaid delivery system. However, we request comment on whether there are other systems that should be noted specifically, or if there are specific circumstances where providing the assistance contemplated in this section is ill-advised or infeasible.

Our proposed regulation at § 422.562(a)(5)(i) includes a list of illustrative examples, at paragraphs (5)(i)(A) through (5)(i)(C), which we do not intend to be an exhaustive list of how a D–SNP would be required to comply with the assistance obligation in § 422.562(a)(5)(i). In paragraph (a)(5)(i)(A), we address explaining to a D–SNP enrollee how to request Medicaid authorization and file an appeal. Our proposed text includes examples of the type of assistance we expect D–SNPs to provide to their enrollees when the enrollees need information and explanations about obtaining Medicaid services. We recognize that state Medicaid systems vary substantially, and that the specific forms of assistance will also vary from market to market. We do not seek to be overly prescriptive in the types of assistance a D–SNP must provide, and our examples are not intended to be exhaustive. We propose, in paragraphs (5)(i)(A)(1) through (5)(i)(A)(3), examples of the types of assistance that

a D–SNP must offer, and upon acceptance or request, provide its enrollees, such as specific instructions on how to contact the entity that may cover the service (for example, the Medicaid managed care plan or a contact in the fee-for-service system), and assistance in obtaining and filling out forms necessary for the next steps in the process.

In paragraph (a)(5)(i)(B), we propose that D–SNPs provide assistance in the actual filing of grievances and appeals. Not all enrollees would need such assistance; for many enrollees, simply receiving information under paragraph (a)(5)(i) would be sufficient. When a D–SNP enrollee needs assistance with the act of filing a Medicaid grievance or appeal, their D–SNP should provide that help. However, the D–SNP is not obligated to represent the enrollee in Medicaid appeals. We welcome comments regarding this proposal; in particular, we ask for comments regarding how D–SNPs that do not have aligned enrollment would comply with this requirement when such entities might have financial and clinical responsibility for the disputed services, potentially presenting a conflict of interest.

In paragraph (a)(5)(i)(C),we propose that the D–SNP assist the enrollee in obtaining documentation in support of a request for authorization or appeal. Obtaining documents such as medical records can be a challenge for any beneficiary, especially for those with limited resources who may lack broadband access to receive large documents electronically, may have unreliable mail service, may not be able to afford printing costs, and may not have easy access to transportation to pick up documents in person. We believe that D–SNP care coordinators are a logical choice to help an enrollee assemble medical documentation and may be particularly well-positioned to assist in compiling records, as they would have insight into the types of documentation enrollees need to support similar requests made to the D–SNP.

The examples listed in proposed paragraph (a)(5)(i)(A) through (C) are not intended to be an exhaustive list, but rather are to provide some leading examples of the assistance we believe any D–SNP should provide. Accordingly, it would not be acceptable for a D–SNP to tell an enrollee simply to contact ''Medicaid'' in general when the enrollee encounters a problem with his or her Medicaid coverage or is obviously in need of assistance in figuring out how to file an appeal of a denial of Medicaid-covered benefits. We invite comments on this proposal, specifically whether the regulation text is clear enough that the examples are not an exhaustive list of methods of assistance that the D–SNP must offer its enrollees, as well as suggestions for other examples of assistance that we should include in regulation or address in subsequent subregulatory guidance.

In proposing these amendments to § 422.562(a)(5), we recognize that offering and providing useful, effective assistance—and therefore compliance with this proposed requirement—may appear challenging. For example, some D–SNPs today may have difficulty determining what type of Medicaid coverage a member has (for example, fee-for-service vs. managed care; which specific managed care plan the enrollees is in; which services are carved out). Without accurate and timely information on the enrollee's Medicaid coverage, it is difficult to effectively help the enrollee navigate, for example, which entity to contact, and what forms are necessary, to pursue coverage or an appeal. Full compliance with our proposal requires that D–SNPs and states maintain data sharing that allows D–SNPs to determine the type and source of Medicaid coverage of their enrollees. However, we believe it is reasonable to expect that D–SNPs, as plans focused on serving dually eligible beneficiaries, take steps to access such information to provide effective care coordination for dual eligible enrollees and to implement more seamless (even if not unified) grievance and appeals systems. Moreover, providing such assistance may further be in a D–SNP's interest, if the enrollee's access to Medicaid-covered services like personal care services and other HCBS prevents an otherwise avoidable hospitalization, for example. We welcome comments on this proposal, suggestions for additional examples of assistance, as well as comments on challenges D–SNPs and others envision in implementing the provisions of proposed paragraph (a)(5).

We also propose language related to enrollees accepting the offer of assistance in proposed paragraph (a)(5)(i). We do not expect or want D–SNPs to implement any processes that might act as barriers to enrollees in accessing assistance nor do we want to create barriers to D–SNPs providing such assistance; if an enrollee does not want the D–SNP's help in resolving an issue, then the D–SNP would not be obligated under our proposal to provide assistance against the enrollee's wishes. At the same time, we do not intend to create any affirmative obligation on the D–SNP to assist enrollees if they decline the offer of assistance. Enrollees are free to decide for themselves how to navigate their Medicaid coverage. In our proposal, the only obligation on D–SNPs is to offer assistance, and when a request is made or an offer of assistance is accepted, to provide it. We welcome comments on whether the regulation text, as we have proposed it, is the best way to achieve this goal.

In paragraph (a)(5)(ii), we propose to specify that the D–SNP's obligation to offer assistance arises whenever the D–SNP becomes aware of an enrollee's need for a Medicaid-covered service. Our proposal includes text explicitly clarifying that enrollees do not need to make a specific request to their D–SNP for assistance. We expect that D–SNPs, as plans with expertise in serving dually eligible beneficiaries, should be able to identify a potential Medicaid coverage issue as part of their regular assessments and care management processes. For example, a D–SNP may become aware that an enrollee is unsatisfied with the personal care services she is receiving based on the work of a care coordinator or from a call or email from the enrollee or enrollee's family. Our proposed regulation text does not explicitly require a D–SNP to use its care coordination or case management programs to identify this type of issue. However, if the issue comes to the attention of the D–SNP, we would expect the plan to offer to assist the enrollee in resolving the coverage issue(s) or grievance given the D–SNP's responsibility, consistent with our proposed definition of a D–SNP at § 422.2, that such a D–SNP provide, as applicable, and coordinate the delivery of Medicare and Medicaid services for its enrollees. We request comments on whether we should include such explicit direction to D–SNPs in the regulation to identify issues that an enrollee is having, or whether our proposed regulation text is sufficiently clear that D–SNPs will understand and meet our goal of providing assistance to an enrollee such that the enrollee can access benefits regardless of whether the benefit is covered by Medicare or Medicaid. We are not proposing any new requirements related to assistance with Medicare covered services. We are also not proposing any new requirements related to services for partial-benefit dual eligible enrollees. Partial-benefit dual eligible enrollees do not qualify for the full range of Medicaid services, and therefore, we do not believe the proposed rule creates any new obligation for D–SNPs to offer assistance for such enrollees. We welcome comments regarding the provisions at proposed

§ 422.562(a)(5)(ii) and the need for any further clarification limiting the scope of § 422.562(a)(5) to full-benefit dual eligible individuals.

In paragraph (a)(5)(iii), we propose to provide further detail on the methods of assistance required by proposed paragraph (a)(5)(i). The methods we propose in the regulation are intended to be examples of what a D–SNP will be required to offer and provide to enrollees and will depend, to some extent, on the needs and preferences of the enrollee. In paragraph (a)(5)(iii)(A), we note that a D–SNP may provide coaching to the enrollee to promote self-advocacy. Some dually eligible enrollees are highly adept at advocating for themselves, and may require only modest assistance—for example, a phone number or direction to an appropriate website—or help with technical terms in explaining why they need a specific piece of equipment. We welcome comments on the methods of assistance and whether further detail is needed. In paragraph (a)(5)(iii)(B) we propose to make explicit a requirement that a D–SNP provide whatever reasonable assistance an enrollee needs in navigating the Medicaid grievance and appeals systems, such as assistance completing forms. We note that existing regulations (for example, §§ 422.111(h)(1)(iii) and 438.406(a)) address the provision of interpretation services. In the context of grievances and appeals, Medicaid requirements also currently require auxiliary aids and services for enrollees who have limited English proficiency or disabilities that require accommodation (§ 438.406(a)).[12] The language in this section is very similar to obligations already required of Medicaid managed care organizations at § 438.406(a). Medicare plans also have existing obligations under Title VI of the Civil Rights Act of 1964 to take reasonable steps to ensure meaningful access by individuals with limited English proficiency and under section 504 of the Rehabilitation Act to take appropriate steps to ensure effective communication with individuals with disabilities, including the provision of auxiliary aids and services. We have opted not to specify the preferred technical forms of assistance that would be required under this proposal, as the evolution of technology and the increases in integration over time may change the analysis of what methods of assistance are reasonable for a D–SNP to be required to provide to its enrollees. However, because D–SNPs are already required to provide similar assistance to their enrollees in other circumstances, we do not anticipate that compliance with this provision should be burdensome to plans. We welcome comments on this matter, including whether and how our goals might be met with more specific regulation text.

In paragraph (a)(5)(iv), we propose to require that a D–SNP provide documentation to CMS upon request that demonstrates how the D–SNP is providing the assistance proposed under paragraph (a)(5)(i).

In paragraph (a)(5)(v), we propose to clarify that D–SNPs are not required to represent enrollees in Medicaid appeals. We welcome comments regarding whether any further clarification is needed on this issue.

(2) Statutory Basis and Scope for Unifying Grievances and Appeals (§ 422.560)

In § 422.560, we propose to add new paragraphs (a)(4) and (b)(5) to address the statutory basis and scope of our proposal to establish unified grievance and appeals processes for a subset of D–SNPs. Specifically, we are proposing a new paragraph (a)(4) to cite section 1859(f)(8) of the Act and provide that the procedures under that section apply in place of otherwise applicable grievance and appeals procedures with respect to items and services provided by certain D–SNPs. We are also proposing to add new paragraph (b)(5) to identify the scope of the new proposed regulations—that is, requirements for applicable integrated plans with regard to unified appeals and grievance procedures. The substance of these proposals is addressed in sections II.A.2.a.(3) through (11) of this proposed rule.

(3) Definitions of ''Applicable Integrated Plan'', ''Integrated Appeal'', ''Integrated Grievance'', ''Integrated Organization Determination'', and ''Integrated Reconsideration,'' and General Requirements for Applicable Integrated Plans (§§ 422.561 and 422.629)

A central challenge to implementing unified grievance and appeals systems for D–SNPs and the Medicaid managed care organization operated by such plan's parent organization is the variety of enrollment scenarios across states. There are only a limited number of D–SNPs in which aligned enrollment, as defined in proposed § 422.2, is possible—that is, a situation when a full-benefit dual eligible individual is enrolled in a D–SNP and receives coverage of Medicaid benefits from the D–SNP or from a Medicaid managed care organization, as defined in section 1903(m) of the Act, operated by the D–SNP's parent organization or by another entity that is owned and controlled by the D–SNP's parent organization. Even fewer D–SNPs operate in states where that State Medicaid Agency mandates such aligned enrollment. With exclusively aligned enrollment, all of the enrollees of the D–SNP also receive Medicaid services through the D–SNP or an affiliated Medicaid managed care organization operated by such plan's parent organization. We believe it is most feasible to unify grievance and appeals systems under exclusively aligned enrollment because one organization is responsible for both Medicare and Medicaid coverage, albeit through separate contracts.

The bulk of D–SNP enrollment, however, is not exclusively aligned. In most states, the majority of D–SNP enrollees have Medicaid coverage either through a different organization's Medicaid MCO, in a prepaid ambulatory or inpatient health plan (PAHP or PIHP), or through a state's Medicaid fee-for-service system. In these circumstances, the D–SNP has no control over the Medicaid grievance and appeals processes. Even a D–SNP that has a Medicaid managed care organization operated by such plan's parent organization available to its enrollees, but whose members may instead enroll in other Medicaid plans, can only unify the procedures for Medicaid appeals and grievances of those enrollees who are also simultaneously enrolled in the Medicaid managed care organization operated by such plan's parent organization. We do not believe it is feasible at this time to implement fully unified grievance and appeals systems for D–SNPs and Medicaid managed care plans that do not have the same enrollees or where the organizations offering the D–SNPs and Medicaid plans are unaffiliated or even competitors.

We propose to add definitions for new terms used in this notice of proposed rulemaking to govern the integrated grievance and appeals processes. In § 422.561 we propose new definitions for ''applicable integrated plan,'' which is the specific type of D–SNP and affiliated Medicaid plan that would be governed by the new integrated grievance and appeals regulations. In our definition of applicable integrated plan, we propose to include only a subset of D–SNPs, that is, only FIDE SNPs and HIDE SNPs with exclusively aligned enrollment, terms that are defined at proposed § 422.2 and described in section II.A.2.a.(1) of this proposed rule. We propose that the

[12] In addition, the Medicaid managed care regulation at § 438.10(d) addresses the requirement to provide translation and assistance in a broader context.

affiliated Medicaid plan be a Medicaid managed care organization, as defined in section 1903(m) of the Act, that is offered by—(1) the D–SNP with exclusively aligned enrollment; (2) the parent organization of such D–SNP; or (3) another entity that is owned and controlled by the parent organization of such D–SNP. Thus, our proposal for unified grievance and appeals procedures would apply only to the enrollees of the subset of D–SNPs that are FIDE SNPs or HIDE SNPs with exclusively aligned enrollment and the affiliated Medicaid managed care organizations through which such enrollees receive their Medicaid services. As we note in our discussion of the proposed definition of aligned enrollment in section II.A.2.a of this proposed rule, we would not consider a D–SNP's companion Medicaid plan to be an applicable integrated plan where it is a prepaid inpatient health plan (PIHP) or prepaid ambulatory health plan (PAHP) in the state's Medicaid program. We solicit comments on our proposed definition of an applicable integrated plan and how it reflects which plans and entities would have to use the unified grievance and appeals procedures we propose in this rule. We also seek comment on whether limiting our proposed policies to MCOs, rather than including PIHPs and PAHPs, is appropriate in light of the statute and our policy goals.

The requirements for non-fully integrated D–SNPs would remain unchanged. This means that there would be different sets of requirements for different types of D–SNPs, and we are proposing these new defined terms to make these separate requirements distinct. We estimate that, currently, this subset of plans comprises a small share of the overall D–SNP market: 37 plans in 8 states, covering approximately 150,000 enrollees nationwide. We believe that these are the plans for which integrated grievance and appeals processes as we propose here are most suitable. We seek comment on our belief that exclusively aligned enrollment provides the most feasible context for unifying grievance and appeals systems and—recognizing that states can organize managed care enrollment policy in a variety of ways—whether our use of the term ''exclusively aligned enrollment'' captures the optimal universe of managed care arrangements for such unification.

For the purpose of differentiating the terminology and procedures within this framework, we propose to establish definitions for ''integrated organization determination,'' ''integrated appeal,'' ''integrated reconsideration,'' and ''integrated grievance'' and apply them exclusively to applicable integrated plans.

Integrated organization determinations would encompass both Medicare organization determinations, as described in § 422.566, and adverse benefit determinations, as defined in § 438.400(b); however, these determinations would be made by applicable integrated plans and would therefore be subject to the integrated organization determination procedures in proposed §§ 422.629, 422.631, and 422.634. These would be the first decisions made by the applicable integrated plan regarding coverage, approval, or payment for a covered service. We propose to define this term by referencing Medicare organization determinations as described in § 422.566, actions as defined in § 431.200, and adverse benefit determinations as defined in § 438.400(b) to parallel the scope of the MA, Medicaid, and Medicaid managed care regulations, rather than by using a specific list of decisions or actions to ensure that the applicable regulations using this term truly unify and integrate the applicable concepts from both the Medicare and Medicaid programs.

Similarly, integrated reconsiderations would be the appeal of the adverse integrated organization determinations by an applicable integrated plan with respect to the health care services the enrollee believes he or she is entitled to receive, including delay in providing, arranging for, or approving the health care services (such that a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for a service. Under our proposal, an integrated reconsideration would be the same as an MA plan's reconsideration (in § 422.580) of an organization determination (defined in § 422.566) and the appeal (defined in § 438.400(b)) of an adverse benefit determination. Integrated reconsiderations would encompass both Medicare reconsiderations, as described in §§ 422.578, 422.580, 422.582, and 422.584, and appeals, as defined for the Medicaid managed care context in § 438.400(b). However, these determinations would be made by applicable integrated plans and therefore subject to the integrated reconsideration procedures in proposed § 422.629 and 422.632 through 422.634.

We propose defining integrated appeals to encompass integrated reconsiderations, and any additional post-plan level unified appeal processes that may be implemented in the future. Our proposed definition is similar to the definition of appeal in MA, at § 422.561, which encompasses both the reconsideration level of the appeal process, as well as additional stages of the appeals process such as review by an independent entity, hearings before ALJs, review by the Medicare Appeals Council and judicial review.

Additionally, we propose to define an integrated grievance as a dispute or complaint that would be defined and covered, for grievances filed by an enrollee in non-applicable integrated plans, under § 422.564 or §§ 438.400 through 438.416. Integrated grievances would not include appeals procedures or QIO complaints, as described in § 422.564(b) and (c), respectively. An integrated grievance made by an enrollee in an applicable integrated plan would be subject to the integrated grievance procedures in §§ 422.629 and 422.630. This means that an integrated grievance would include a Medicare or Medicaid complaint or dispute about the applicable integrated plan or the enrollee's providers that is not a complaint or dispute about such plan's coverage determination (referred to as an integrated organization determination in this proposed rule).

Our proposed definitions for integrated grievance, integrated organization determination, and integrated reconsideration are intended to replicate the scope and meaning of the parallel terms in parts 422 subpart M and part 438 subpart E regarding the appeals and grievance procedures required of, respectively, MA organizations and Medicaid managed care plans because we are proposing that the regulations and procedures proposed here take the place of those part 422 and part 438 procedures for applicable integrated plans. We solicit comment whether our proposal adequately accomplishes this.

We propose at § 422.629 to establish general requirements for applicable integrated plans, as defined in § 422.561. In paragraphs (a) and (b), we propose language that sets forth the scope of the requirements and general process that applicable integrated plans must implement. In paragraph (a)(1), we propose to specify that the proposed rules apply in lieu of the general requirements for MA organizations at §§ 422.564, 422.566(c) and (d) and 422.568–422.596, and Medicaid managed care plans at §§ 438.404–438.424, and encompass integrated grievances, integrated organization determinations, and integrated reconsiderations. In paragraph (b), we set forth the general requirement that applicable integrated plans create

integrated processes to administer these grievance and appeals requirements.

In proposed paragraph (c), we address an overarching question about whether a state may establish requirements that are different for the applicable integrated plan(s) using the state Medicaid agency contract required under § 422.107. Specifically, we propose to apply the flexibility offered to states under Medicaid regulations, which establish a floor for enrollee protections, while also offering states flexibility to impose more stringent requirements for timeframes and notices so long as they are more protective of beneficiaries. States may already have laws in effect that take advantage of this flexibility. For example, under § 438.408(b)(2), a Medicaid managed care plan must resolve a standard appeal within a timeframe established by the state, but not to exceed 30 calendar days. The maximum timeframe for an MA organization to decide a standard reconsideration is also no later than 30 calendar days (§ 422.590(a)(1)). Ohio Medicaid, however, sets this timeframe for its Medicaid managed care plans at 15 days unless an extension is granted.[13] If an integrated appeals process under this proposal were to be implemented in Ohio, we would allow adoption of that 15-day standard for all standard integrated appeals. We believe that by preserving state flexibility in adopting more stringent, beneficiary-protective requirements, we are adhering to the direction set forth in sections 1859(f)(8)(B)(ii)(I) and (II) of the Act for us to take into account differences in state plans under Title XIX. Finally, in paragraph (c), we propose to codify the opportunity for states to establish standards that differ from the standards set forth in these regulations in its State Medicaid Agency contract, per § 422.107, with the applicable integrated plans. We are soliciting comments on our proposed approach, and specifically how we propose to allow state flexibilities to be incorporated into the unified procedures for an applicable integrated plan.

In paragraph (d), we propose that the applicable integrated plan provide the enrollee who is requesting the integrated reconsideration a reasonable opportunity, in writing and in person, to present evidence and testimony and make legal and factual arguments in support of their appeal. On this topic, both the MA standard at § 422.586 and the Medicaid standard at § 438.406(b)(4) are similar in granting this right to the enrollee for the plan-level appeal; however, under Medicaid regulation, this right extends to grievances, whereas in MA, it does not. We also propose to require that applicable integrated plans inform enrollees of the limited time available for these opportunities in cases were the timeframe is expedited, similar to § 422.586 and § 438.406(b)(4).

In paragraph (e), we propose to require applicable integrated plans to provide reasonable assistance to the enrollee with respect completing and submitting their integrated appeals and integrated grievances, as well as on navigating this process. This proposal would impose on applicable integrated plans a similar standard as applies to Medicaid managed care plans pursuant to § 438.406(a). As discussed earlier, plans have existing obligations under Title VI of the Civil Rights Act of 1964 and section 504 of the Rehabilitation Act, so we do not believe that incorporating this beneficiary protection to this context would create an unreasonable burden. Here, as also discussed earlier in this preamble related to proposed § 422.562(b)(3)(ii), we opted not to specify the preferred technical forms of assistance, as preferred standards can change as technology evolves.

We propose at paragraph (f) a general rule, using cross-references to the requirements in §§ 422.560, 422.561, 422.562, 422.566, and 422.592 through 422.626, to specify the regulations that apply to the applicable integrated plan for grievance and appeals processes unless otherwise noted.

We propose at paragraph (g) to require applicable integrated plans to send the enrollee an acknowledgement of receipt in writing for all integrated grievances and integrated reconsiderations. Currently, the Medicaid regulation at § 438.406(b) requires acknowledgement of grievances and appeals, and MA guidance explains the need for written acknowledgement of oral requests for reconsideration (see Medicare Managed Care Manual Chapter 13, section 70.2). Section 1859(f)(8)(B)(iii)(IV) of the Act, as added by section 50311(b) of the Bipartisan Budget Act of 2018, specifically calls for unified timelines and procedures for acknowledgement of appeals and grievances We propose to adopt the standard currently in § 438.406(b) for applicable integrated plans, and we propose to clarify that the acknowledgement should be in written form. We believe that this requirement is both beneficial to enrollees and assists them in determining the status of the grievance or appeal, and thus is in alignment with the standard in section 1859(f)(8)(B) of the Act for the unified procedures.

In paragraph (h), we propose to adopt Medicaid's grievance and appeals recordkeeping requirements, as required for Medicaid managed care plans at § 438.416, to require applicable integrated plans to maintain records of integrated appeals and grievances and review them as part of their ongoing monitoring procedures. The requirements that we propose also align with relevant MA requirements for grievance recordkeeping (see § 422.564(g)) and are consistent with the MA requirements for general recordkeeping (see § 422.504(d)).

We propose in paragraphs (i) and (j) to incorporate similar provisions as are imposed on Medicaid managed care plans pursuant to §§ 438.410(b) and 438.414 regarding relationships between the plan and its contracted network providers. Specifically, in paragraph (i), we propose to prohibit an applicable integrated plan from taking any punitive action against a provider for requesting an integrated organization determination or integrated reconsideration, similar to the provisions in §§ 422.570(f) and 438.410(b). We believe that these standards would establish beneficiary protections in the context of applicable integrated plans because the threat of punitive action might otherwise discourage a provider from pursuing, on the enrollee's behalf, or supporting an enrollee in pursuing, an integrated appeal for a needed item or service. We also propose requiring, in paragraph (j), such a plan to disclose information about its appeals and grievances procedures at the time it enters into a contract with a provider or subcontractor. We propose to include specific topics which must be covered in this information to providers, and these specific topics are the same as in existing Medicaid regulations (see § 438.414, which cites to § 438.10(g)(2)(xi) for this purpose). Although there are no specific MA regulations that impose the same requirements on D–SNPs, Medicare regulations require that MA organizations communicate information on medical policy and medical management procedures (see § 422.202(b)). We believe this proposed requirement aligns with the goals of the statute in educating providers to help ensure an easily navigable system for enrollees, where providers understand the system and their role in it.

In paragraph (k), we propose regulatory standards controlling who must review an integrated organization determination. The part 422 and part

[13] See Ohio Administrative Code 5160–58–08.4(D)(6), available at *http://codes.ohio.gov/oac/5160-58-08.4*.

438 regulations each impose standards of this type but they are not identical. In developing our proposal, we sought to combine the MA and Medicaid managed care requirements for who must review an organization determination. This new requirement would apply to grievances, as is currently the case § 438.406 but not in the applicable MA regulations. In paragraph (k)(1), we propose to include the requirement from Medicaid (§ 438.406(2)(iii)) that any individual who reviews an integrated appeal or grievance must consider all information submitted by the enrollee, regardless of whether the information was previously made available to the plan. In paragraph (k)(2), we propose to include the requirements for reviews of Medicaid grievances (from § 438.406(2)) for who can review a grievance to integrated grievances. There are no requirements in Medicare for who can review a grievance; however, we believe that ensuring that the individual who reviews a grievance has appropriate expertise for the circumstances is an important enrollee protection that should be applied to integrated grievances.

In paragraph (k)(3), we propose to include the existing requirements from MA (§ 422.566) for who can review an organization determination. There are no requirements in Medicaid for who can review a service authorization request; however, we believe that ensuring that the individual who reviews an integrated organization determination has appropriate expertise for the circumstances is an important enrollee protection that should be applied to integrated organization determination. We also propose language that, in accordance with current MA regulations (§ 422.566(d)) requires that physicians or other health care professionals who review integrated organization determinations have an unrestricted license and be acting within the scope of that license.

In paragraph (k)(4) we propose to combine existing MA and Medicaid requirements for who can review a reconsideration or adverse benefit determination since both sets of existing regulations have relevant requirements. MA and Medicaid requirements are largely similar for individuals who review appeals be someone who was not involved in a previous level of review, and, in cases involving medical necessity, someone who has appropriate clinical expertise (§§ 422.590 and 438.406(b)(2)). These existing requirements are reflected in our proposed requirements.

(4) Authorization for Filing Appeals (§ 422.629(l))

We propose at § 422.629(l) to combine the MA and Medicaid requirements, such that a treating provider or authorized representative can file an appeal on behalf of an enrollee. Medicaid managed care rules at § 438.402(c)(1)(ii) require written authorization from the enrollee where a physician or other authorized representative files an appeal involving a benefit to which the enrollee may be entitled. MA rules at § 422.566(c), however, allow a treating provider to file an appeal on behalf of an enrollee without written authorization from the enrollee, although the provider is required to provide notice to the beneficiary. We believe the MA requirement is generally more beneficial to beneficiaries, as it imposes fewer procedural requirements to filing an appeal for the enrollee, for example, if an enrollee has factors that make signing an authorization difficult. The Medicaid requirements, on the other hand, may serve to mitigate the risk that a provider would file an appeal against an enrollee's interest and without an enrollee's consent, particularly to take advantage of the Medicaid provisions that allow a benefit to continue while the appeal is pending, an issue we discuss in more detail in section II.A.1.b.(7) of this preamble for proposed § 422.632. We believe our proposal reduces barriers for enrollees to have appeals filed, while also accounting for risk to enrollees by requiring the enrollee's written consent only when there is a request for continuation of benefits. However, we invite comments as to whether an approach closer to Medicaid's, in which written authorization would be required in all cases when a provider files an appeal on behalf of a beneficiary, would be preferable.

(5) Integrated Grievances (§ 422.630)

At § 422.630, we propose to largely parallel Medicare and Medicaid requirements where these requirements are the same with regard to the treatment of integrated grievances. Where MA includes a requirement that Medicaid does not, or vice versa, or where the MA and Medicaid regulations conflict, we propose applying the requirement that best aligns with the principles and statutory requirements discussed in section II.A.1.b. of this preamble. For integrated grievances, we specifically propose:

- At paragraph (a), to establish the general purpose of the regulation, similar to § 438.402(a) and § 422.564(a), by requiring that an applicable integrated plan provide meaningful procedures for timely hearing and resolving integrated grievances filed by an enrollee. We propose to define the scope of the required procedures as being applicable to any grievances between the enrollee and the plan or any entity or individual through which the applicable integrated plan covers health care services. We propose this requirement for the applicable integrated plan to be responsible for ensuring timely and appropriate resolution of a grievance even if the grievance pertains to an act or decision by one of the applicable integrated plan's contracted providers or vendors. Our proposed regulation text mirrors the Medicare Advantage language at § 422.564(a) for this requirement. We believe that clearly ensuring that an applicable integrated plan is ultimately responsible for resolving all grievances related to services that it is responsible for providing is an important enrollee protection and provides enrollees with an easily navigable, single pathway for resolution of grievances, consistent with sections 1859(f)(8)(B)(ii)(I) and (III) and (iii)(II) of the Act.
- At paragraph (b), to provide that an enrollee may file a grievance at any time. The relevant Medicaid regulation (§ 438.402(c)(2)(i)) allows a grievance to be filed at any time, while the MA regulation (§ 422.564(d)(a)) limits grievance filing to within 60 days of the event at issue. We propose to impose the standard that is more protective of enrollees on applicable integrated plans.
- At paragraph (c), to allow grievances orally or in writing, in alignment with Medicare and Medicaid requirements, while allowing for integrated grievances related to Medicaid benefits to be filed with the state, in states that have processes in place in accordance with § 438.402(c)(3). We propose to include current state processes, where they exist, for enrollees to file grievances with the state that relate to Medicaid benefits. The option for a state to accept grievances currently exists in the Medicaid regulations (see § 438.402(c)(3)). We believe that this is an important protection for enrollees and, in proposing requirements that are most protective to the enrollee and take into account differences in state plans, we are proposing to leave this option for filing grievances open to enrollees, if it is otherwise an option in the state's Medicaid program.
- At paragraph (d), we propose to largely parallel the Medicare Advantage requirements (at § 422.564(f)) for when an enrollee can file an expedited

grievance because we find them a protection for beneficiaries. Medicare Advantage regulations require that plans provide for expedited grievances in cases when: (1) A plan extends the timeframe for resolving an organization determination or reconsideration, or (2) the grievance involves a refusal to grant an enrollee's request for an expedited organization determination or reconsideration (§ 422.564(f)). The Medicaid managed care regulations do not include a federal provision for expedited grievances.

- At paragraph (e)(1), to parallel Medicare Advantage's 30-day timeframe for resolving the grievance and Medicare Advantage's requirements for how the applicable integrated plan must respond to grievances, depending on how the grievance is received and the basis upon which the enrollee filed the grievance; again we find the Medicare Advantage provision to be more protective of enrollees. Medicaid requires plans to resolve grievances within 90 days (§ 438.408(b)(1)), while Medicare Advantage regulations require that plans resolve them within 30 days (§ 422.564(e)). Medicare Advantage regulations address the issue of how a managed care plan must respond to grievances depending on how the grievance was received and the issue in dispute (§ 422.564(e)(3)). Medicaid leaves requirements for responding to grievances to the state to determine, provided that the requirements set by the state meet, at a minimum, the requirements described at § 438.10 (§ 438.408(d)(1)).
- At paragraph (e)(2), to include a provision permitting the applicable integrated plan to extend the time period in which a determination on an integrated grievance must be issued to the enrollee. We propose this provision to parallel Medicare Advantage (§ 422.564(e)(2)) and Medicaid managed care (§ 438.408(c)(1)) requirements that extend the grievance resolution timeframe by up to 14 days. We also propose to adopt a combination of the Medicare Advantage and Medicaid managed care requirements for how an applicable integrated plan must notify an enrollee of an extension. MA regulations require that the MA plan immediately notify the enrollee in writing of the reason for the delay (§ 422.564(e)(2)), while Medicaid managed care requires notice within 2 calendar days (§ 438.408(c)(2)). We have combined those requirements in our proposal here, such that applicable integrated plans must notify enrollees immediately, but no later than within 2 calendar days, which we believe to be in line with the principles identified in section 1859(f)(8)(B)(iii) of the Act for timely, clear notification for enrollees.

We invite comments on these topics, specifically whether the proposed regulation text accurately incorporates the standards from the underlying part 422 or part 438 regulation that are more beneficial to the enrollee.

For each of these issues, we propose to adopt the requirement that is most protective for enrollees and that ensures timely, clear, and understandable resolution and notification. We propose to give enrollees the most flexibility in filing a grievance by not putting any limits on when it can be filed and providing clear guidance to ensure enrollees can support their cases with relevant information. We also propose timeframes that ensure plans resolve the grievance quickly and provide clear notice to enrollees of the resolution. We solicit comment on whether we have adequately captured all relevant enrollee protections here.

(6) Integrated Organization Determinations (§ 422.631)

In proposed § 422.631, we describe the procedures applicable integrated plans would follow in making an integrated organization determinations. In paragraph (a), we propose that, as part of a unified process, all requests for benefits covered by applicable integrated plans must be subject to the same integrated organization determination process.

In paragraph (b), we propose to adopt the MA provisions at § 422.568(a) allowing an enrollee to request an integrated organization determination either orally in writing, but requiring requests for payment to be made in writing. The Medicaid managed care regulations do not include specific rules in this area.

In paragraph (c), we propose to articulate the standard for making an expedited organization determination. Both MA (at § 422.570(c)) and Medicaid (at § 438.210(d)(2)) have similar standards for an expedited organization determination, and we propose to reflect the standards of both programs. This proposed provision tracks existing MA regulation language more closely than the Medicaid language with respect to who can make the request (proposed paragraph (c)(1)), and how it should be considered and decided (proposed paragraph (c)(3)), though we believe the MA and Medicaid requirements are functionally the same. At paragraph (c)(2), we propose to include the more specific language from the MA regulations at § 422.570(b)(1) that the request to expedite the appeal can be made orally or in writing. We invite comments regarding alternative phrasing.

In paragraph (d), we propose rules regarding timeframes and notices when resolving integrated coverage determinations. In paragraph (d)(1), we propose to require that an applicable integrated plan send a written integrated notice when the organization determination (standard or expedited) is adverse to the enrollee. We propose to include text specifically identifying as adverse determinations requiring a notice any decision to authorize a service or item in an amount, duration, or scope that is less than the amount requested or previously requested or authorized for an ongoing course of treatment. We also propose to include text specifying, consistent with Medicaid managed care requirements (§ 438.404(c)(5)), that the applicable integrated plan must send an integrated determination notice when it fails to make a timely decision, since such a failure constitutes an adverse decision, and that the enrollee may then request an integrated reconsideration. The proposed notice would include information about the determination, as well as information about the enrollee's appeal rights for both Medicare and Medicaid covered benefits. Though integrating information on Medicare and Medicaid appeal rights would be a new requirement if this proposed requirement is finalized, we propose content requirements for the notice that generally largely align with current requirements in Medicaid (§ 438.404(b)) and MA (§ 422.572(e)). We also propose that the notice be written in plain language and available in a language and format that is accessible to the enrollee consistent with 1859(f)((8)(B)(iii)(III) of the Act.

In paragraph (d)(2), we propose timelines for sending this notice that largely align with both existing Medicare and Medicaid requirements. We propose, in paragraph (d)(2)(i)(A), to require that applicable integrated plans send a notice of an integrated organization determination at least 10 days before the date of action if a previously authorized benefit is being reduced, suspended or terminated, as is currently required for Medicaid managed care plans under § 438.404(c), with some exceptions in accordance with §§ 431.213 and 431.214. Exceptions under § 431.213 include circumstances where the enrollee cannot, or does not wish to, be reached—for example, there exists factual information confirming the enrollee's death or the enrollee is no longer eligible for services, or if the State Medicaid Agency determines that

the beneficiary has been accepted for Medicaid services in another jurisdiction. Exceptions under § 431.214 allow for less advance notice to the enrollee in cases of probable fraud. This standard for the timing of these notices (within 10 days subject to specific exceptions) is adopted from Medicaid and aligns with the timing for enrollees to request (under § 438.420) continuation of a previously authorized benefit while the integrated reconsideration is pending because it gives the enrollee enough time, upon receiving the notice, to request that the benefit continue without a potential gap in the benefit. We propose, in paragraph (d)(2)(i)(B), to require that applicable integrated plans send the notice as expeditiously as the enrollee's health condition requires but no later than 14 calendar days from receipt of the request for a standard integrated organization determination, and propose to permit extensions, in proposed paragraph (d)(2)(ii), in circumstances that largely parallel those that exist in Medicare and Medicaid currently. In paragraph (d)(2)(iii), we propose requirements for notice in cases of extension which largely parallel current MA and Medicaid requirements at § 422.572(b)(2) and § 438.404(c)(4)(i), respectively. Both MA and Medicaid currently require that the health plan notify the enrollee of the delay and the right to file a grievance. Section 422.631(d)(2)(iii)(A) as proposed largely parallels § 422.572(b)(2), which provides more specific direction on timing of the notice. We are proposing to apply the MA requirement that the enrollee be notified of the right to file an expedited grievance in these instances. We also propose in paragraph (d)(2)(iii)(B) regulatory text controlling when the notice of the determination must be sent in cases where the applicable integrated plan takes an extension.

In paragraph (d)(2)(iv)(A), we propose the deadline for issuing notice of expedited integrated organization determinations. Both MA and Medicaid require expedited organization determinations (or adverse actions) within 72 hours of the request, with the possibility of extending that timeframe by 14 calendar days. We propose, at paragraph (d)(2)(iv)(B), to mirror the MA requirements (§ 422.570(d)), with required procedures when an applicable integrated plan denies a request for expediting an organization determination. In paragraph (d)(2)(iv)(C) we propose to include requirements, which parallel MA requirements (§ 422.572(d)), for applicable integrated plans when obtaining necessary information from noncontract providers. These requirements specify that the applicable integrated plan must reach out to a noncontract provider within 24 hours of the initial request for an expedited integrated organization determination. Though Medicaid managed care regulations to not contain a similar requirement, Medicaid managed care plans currently must resolve expedited appeals under the same timeframes and, therefore, should already be reaching out to providers for information necessary to process expedited appeals in a similarly timely manner.

(7) Continuation of Benefits Pending Appeal (§ 422.632)

Section 50311(b) of the Bipartisan Budget Act of 2018 amended section 1859(f) of the Act by creating a new paragraph (8)(B)(iv) requiring that the unified appeals procedures we develop with respect to all benefits under Medicare Parts A and B and Title XIX that are subject to appeal under such unified procedures incorporate provisions under current law and implementing regulations that provide continuation of benefits pending appeal under Titles XVIII and XIX. We interpret this provision as requiring CMS to apply continuation of benefits to all Medicare Parts A and B and Medicaid benefits under our proposed unified appeals processes. The statutory language ''with respect to all benefits under parts A and B and title XIX subject to appeal under such procedures'' modifies the verb ''incorporate.'' Therefore, we interpret the provision as requiring CMS to incorporate statutory and regulatory provisions for continuation of benefits into the unified appeal procedures for all Parts A and B benefits, and not only those benefits that are already permitted to be continued under current law (Medicaid benefits and limited Medicare benefits, as described in more detail later in this section of the proposed rule).

We considered current laws and implementing regulations related to continuation of benefits under Medicare and Medicaid and found that Medicare's continuation of benefits provisions are of limited relevance, but that there are significant Medicaid provisions that must be incorporated in our integrated standards. Continuation of benefits exists in very limited circumstances in Medicare currently. A Medicare beneficiary can receive an extension of inpatient hospital stays when the beneficiary appeals a notice of discharge to the Quality Improvement Organization (QIO) under §§ 405.1205 through 405.1208 and §§ 422.620 and 422.622. We do not propose any changes to the existing QIO process, as its specialized nature does not lend itself readily to expansion to other services such as those covered by Medicaid.

Medicaid's continuation of benefits provisions are considerably more comprehensive, and we propose to incorporate them into this unified appeals process. These Medicaid rules, found in §§ 431.230 and 431.231 (general) and § 438.420 (managed care), are grounded in constitutional due process principles articulated in Goldberg v. Kelly, 397 U.S. 254 (1970), that recognize the importance of allowing people with limited financial resources to challenge a decision prior to the decision taking effect. Under § 438.420, a Medicaid managed care plan is required, upon request of the enrollee, to cover certain Medicaid benefits while an appeal is pending, provided that: (1) The enrollee files the request for an appeal timely in accordance with § 438.402(c)(1)(ii) and (c)(2)(ii); (2) the appeal involves the termination, suspension, or reduction of previously authorized services; (3) the services were ordered by an authorized provider; (4) the period covered by the original authorization has not expired; and (5) the enrollee timely files for continuation of benefits.

We also note that continuation of benefits has been included as part of the integrated appeals process in the Financial Alignment Initiative demonstrations, under processes that largely parallel what we are proposing in these regulations. We request comment on our interpretation of the statutory requirements related to continuation of benefits pending appeal.

Accordingly, we propose that the existing standards for continuation of benefits at § 438.420 apply to applicable integrated plans for Medicare benefits under Parts A and B and Medicaid benefits in our proposed integrated appeals requirements at § 422.632. Under our proposal, as is applicable to Medicaid managed care plans currently, if an applicable integrated plan decides to stop (as a termination or suspension) or reduce a benefit that the enrollee is currently authorized to receive, the enrollee could request that the benefit continue to be provided at the currently authorized level while the enrollee's appeal is pending through the integrated reconsideration. The enrollee would be required to make a timely request for the continuation, as further detailed below.

We anticipate that this provision will simplify the appeals process for both

plans and beneficiaries, as it will be unnecessary to determine which ongoing benefits are subject to continuation pending appeal. This has been our experience in the Financial Alignment Initiative demonstrations. In addition, as we note in the Regulatory Impact Analysis, relatively few Medicare benefits are continuing in nature, and we therefore do not anticipate a significant financial cost related to the implementation of this provision by applicable integrated plans.

We propose, at paragraph (a), a definition for ''timely files.'' This definition would mirror the definition at § 438.420(a), with minor revisions to make the text applicable to applicable integrated plans instead Medicaid managed care plans.

We propose, at paragraph (b), to require a previously authorized service covered under Medicaid or Medicare Part A or Part B, excluding supplemental benefits as defined at § 422.103, to be continued pending an appeal of a termination of those services. We propose to require that the continuation of these services as a covered benefit would be conditioned on the same five criteria listed in § 438.420 being met.

We propose, at paragraph (c), to require that an applicable integrated plan continue such services pending issuance of the integrated reconsideration. We note that for Medicaid managed care plans that are not applicable integrated plans, continuation of these services after the integrated reconsideration and pending resolution of the state fair hearing is controlled by § 438.420(c). Our proposal for continuation of services pending appeal would provide a unified, consistent rule for Medicaid and Medicare Part A and Part B benefits, excluding supplemental benefits defined in § 422.103, for the duration of the unified appeals process proposed here for all plan level appeals. Proposed § 422.632(c)(2) therefore provides that continuation of services ends when the applicable integrated plan issues an adverse integrated reconsideration. If the applicable integrated plan finds in favor of the enrollee, benefits would continue in accordance with the favorable integrated reconsideration. In proposed § 422.632(c)(3), we propose requirements for Medicaid-covered benefits to continue after the applicable integrated plan issues an adverse integrated reconsideration, mirroring the requirements currently in Medicaid managed care regulations (see § 438.420(c)(2)). The enrollee must make the request and file for a state fair hearing within 10 calendar days after the applicable integrated plan sends the notice of the integrated reconsideration. We also propose to mirror requirements from § 438.420 for how long Medicaid-covered benefits must continue by requiring that the benefits continue until the enrollee withdraws the request for the state fair hearing or until the state fair hearing decision is issued.

We considered alternative approaches to implementing benefits pending appeal, and we believe integrating through the plan-level reconsideration stage of the appeal process is the most feasible approach at this time. The right for a Medicaid beneficiary to have Medicaid benefits continue through a state fair hearing, which is the second level of appeal for an enrollee, would not be impacted by this proposal. The process that we propose for an enrollee's benefits to continue during the state fair hearing process mirrors the current process under Medicaid regulations at § 438.420.

In proposed paragraph (d), we address whether an applicable integrated plan can seek recovery for the costs of services provided while an appeal is pending. Medicaid regulations allow states to determine whether or not a plan, or the state, can seek recovery for the costs of services provided pending appeal (§ 431.230(b)). If a state permits such recovery under managed care, plans must inform enrollees of this possibility (§ 438.420(d)). As noted in the preamble to the 2016 final Medicaid managed care rule, such notices can have the effect of deterring enrollees from exercising the right to appeal.[14] Moreover, Medicare's provision allowing benefits to continue is limited, as noted earlier, to an extension of inpatient hospital stays when the beneficiary appeals a notice of discharge to the Quality Improvement Organization (QIO) under §§ 405.1205 through 405.1208, and 422.620 and 422.622.[15] Finally, in a number of our Financial Alignment Initiative demonstrations, we and our state partners have explicitly declined to allow MMPs to recover of the costs of services provided pending appeal. Neither MMPs nor states have noted any adverse impact on the costs of services provided pending appeal. Therefore, in paragraph (d), we propose to prohibit recovery of the costs of services provided pending the integrated reconsideration and, for Medicaid-covered benefits, any state fair hearing, to the extent that services were continued solely under § 422.632, for all applicable integrated plans and state agencies.

We considered several alternatives to this approach. We considered proposing to use the same rule as § 438.420(d) and applying it to all services provided pending appeal by applicable integrated plans. Under this alternative, a state's Medicaid recoupment policy would also apply to Medicare benefits provided by an applicable integrated plan pending appeal. However, there is no recoupment provision under Medicare that parallels the recoupment process under Medicaid managed care. As we noted earlier, continuation of services without imposing financial liability on the enrollee in Medicare exists in the narrow circumstances related to extension of inpatient hospital stays when the beneficiary appeals a notice of discharge to the Quality Improvement Organization (QIO). If an enrollee files a timely request for QIO review of the discharge, the enrollee is not responsible for the costs of the hospital services during the QIO review, even if the QIO ultimately finds that the hospital stay should not be continued (§ 422.422(f)). Developing a recoupment policy in Medicare, and communicating it to enrollees, could become administratively complex while offering little benefit to enrollees or plans, considering the limited financial resources of dually eligible enrollees.

We also considered adopting the Medicaid rule at § 438.420(d) only for services provided under Title XIX—that is, Medicaid-covered services. This approach would preserve state flexibility, but it would risk creating administrative complexity for plans and confusion for enrollees, as it would necessitate differentiating between services for which financial recovery was possible and those for which it was not. We invite comments on our proposed approach to prohibit the recovery of the costs of services provided pending appeal, our considered alternatives, and any other possible approaches.

[14] 81 FR 27512 (May 6, 2016).

[15] We note that while regulations at 42 CFR 405.1200 through 405.1204 and 422.624 and 422.626 address appeal rights for Medicare beneficiaries related to terminations of certain facility services and potential continuation of services pending those appeals, those regulations generally require the beneficiary to pay for services received after the date and time designated on the termination notice him or herself unless the beneficiary prevails on the appeal. As an individual always has the right to choose to receive non-covered services when bearing financial responsibility for those services, we believe these scenarios are not truly continuations of benefits pending appeal as the services might not be covered.

(8) Integrated Reconsiderations (§ 422.633)

In proposed § 422.633, we lay out our proposed provisions for an integrated reconsideration process for applicable integrated plans. As with other provisions, we compared relevant Medicare and Medicaid provisions, and where they differ, we chose to adopt the policy that is most protective of the beneficiary.

In paragraph (a), we propose that applicable integrated plans may only have one plan level of appeal. This provision is consistent with § 438.402(b), which prohibits more than one plan level of appeals, and § 422.590, which permits only one internal reconsideration before an adverse decision is subject to review by the independent review entity.

In paragraph (b), we propose to adopt a rule similar to § 438.402(c)(1)(i)(B) regarding the permissibility of external medical reviews: Medicaid managed care plan enrollees may be offered an opportunity to elect external medical review under a state external review process. Under our proposal, the ability to elect external medical review would apply only to Medicaid covered services that are the subject of an adverse integrated reconsideration issued by an applicable integrated plan because D–SNPs, like all MA plans, are not subject to state external review procedures.[16]

In paragraph (c), we propose a right for each enrollee, and their representatives, to review the medical records in the enrollee's case file, consistent with the protection for Medicaid enrollees under § 438.406(b)(5). We believe that this protection for Medicaid enrollees in a managed care plan is appropriate for dually eligible enrollees and should apply to applicable integrated plans. In particular, we propose adopting Medicaid's provision prohibiting plans from charging for copies of records, as we believe the policy applicable for MA plans, which permits plans to charge beneficiaries reasonable copying fees, is inappropriate and less protective of dual eligible individuals, who typically have limited income. We invite comments on this proposal.

In paragraph (d)(1), we propose timelines for filing for a standard integrated reconsideration that, consistent with both MA (at § 422.582(b)) and Medicaid managed care (at § 438.402(c)(2)(ii)) regulations, would require that an integrated reconsideration be filed within 60 days of the date of the denial notice. We propose, in paragraph (d)(2), that oral inquiries seeking to make an integrated reconsideration be treated as integrated reconsiderations; this is generally consistent with § 438.406(b)(3), which we find to be the more protective of enrollees than the MA provision at § 422.582(a) which gives MA plans discretion in deciding to accept oral requests for reconsideration. We believe that applying the Medicaid rule to applicable integrated plans is appropriate because initiating an integrated reconsideration orally may be the easiest way for enrollees to start the integrated reconsideration process quickly, and timely filing can be especially important to ensure aid continues pending the integrated reconsideration resolution under proposed § 422.632. We are not proposing to include the language in § 438.406(b)(3) requiring beneficiaries to provide written confirmation of oral requests because such a requirement would be inconsistent with MA policy that directs plans that do accept oral requests for reconsideration to provide written confirmation to the beneficiary (see Medicare Managed Care Manual Chapter 13, section 70.2). We propose, in paragraph (d)(3), to include current requirements from MA (at § 422.582(c)) that allow for extending the timeframe for an enrollee, or a physician acting on behalf of an enrollee, to file a late reconsideration. As in MA, we propose to allow late filing when a party to the integrated organization determination or a physician acting on behalf of the enrollee can show good cause for the extension and makes the request in writing. We find that this is an important beneficiary protection that should be applied to our proposed integrated process.

In paragraph (e), we propose to address procedures for filing expedited integrated reconsiderations. Both MA (at § 422.584) and Medicaid (at § 438.408(b)(3)) regulations permit filing of expedited appeals. The MA regulation provides greater detail regarding how plans are to consider requests for expedited reconsiderations. The proposed language in paragraphs (e)(1), and (e)(2) aligns with § 422.584 in permitting the enrollee or health care provider to file a written or oral request for an expedited reconsideration. The proposed language in paragraph (e)(3) aligns with § 422.584 in setting the standard that the applicable integrated plan must use in deciding whether to expedite the integrated reconsideration. We invite comments regarding whether additional specificity or harmonizing between Medicare and Medicaid's requirements is needed in this area.

In paragraph (e)(4), we propose notice requirements related to requests for expedited integrated reconsiderations. We propose requirements that parallel Medicaid managed care requirements for notice to the enrollee when the request for an expedited integrated reconsideration is denied (§ 438.410(c)(2))—specifically, that the plan must give prompt oral notice and written notice within 2 calendar days and transfer the matter to the standard timeframe for making an integrated reconsideration (that is, the timeframe specified in paragraph (f)(1)). The MA requirements for notice, when an enrollee's request for an expedited integrated reconsideration is denied, are for the plan to provide prompt oral notice and, subsequently, written notice within 3 calendar days (§ 422.584(d)(2)). We find that the Medicaid managed care requirements are more protective for enrollees by requiring faster notification when the request to expedite is denied. We propose to apply the MA requirements for what applicable integrated plans must include in the written notice to enrollees when the request to expedite the integrated reconsideration is denied (§ 422.584(d)(2)). The MA requirements for the contents of this notice are more extensive than the Medicaid managed care requirements (§ 438.410(c)(2)). We find the additional content requirements to be more protective of enrollees by providing them more information on options, and also helping to make the process more navigable for enrollees.

In paragraph (e)(5) we propose to include requirements, which mirror MA requirements (§ 422.590(d)(3)), for applicable integrated plans when obtaining necessary information from noncontract providers. These requirements specify that the applicable integrated plan must reach out to a noncontract provider within 24 hours of the initial request for an expedited integrated reconsideration. Though Medicaid managed care regulations do not contain a similar requirement, Medicaid managed care plans currently must resolve expedited appeals under the same timeframes and, therefore, should already be reaching out to providers for information necessary to process expedited appeals in a similarly timely manner.

In paragraph (f), we propose timelines and procedures for resolving an integrated reconsideration request. We propose specific requirements for applicable integrated plans. Both MA (at § 422.590(a)) and Medicaid (at § 438.408(b)(2)) require resolution of

[16] Section 1856(b)(3) of the Act preempts state regulation of Medicare Advantage plans.

pre-service standard appeal requests within 30 calendar days. We propose the same rule in paragraph (f)(1), with the addition of a provision mirroring § 422.590(a)(2), that the integrated reconsideration decision be issued as expeditiously as the enrollee's health requires but no later than 30 calendar days from the date the applicable integrated plan receives the request for the integrated reconsideration.

However, MA and Medicaid managed care differ in the timeframes within which plans must resolve post-service appeals (that is, appeals related to payment requests). Medicaid regulations at § 438.408(b)(2) do not distinguish between pre-service and post-service appeals—all appeals must be resolved within 30 calendar days. In contrast, while MA regulations require that plans resolve standard reconsiderations within 30 calendar days for pre-service appeals, plans have 60 days to resolve post-service denials of payment. Although we do not believe the volume of appeals for payment is high for individuals dually eligible for Medicare and Medicaid, it is more protective for enrollees to have all integrated reconsiderations resolved in 30 calendar days, particularly given what may be significant financial needs for the individual. Similarly, we are not proposing to incorporate into the unified appeals process MA's regulation that expedited organization determinations are not required in post-service payment cases. Again, we do not believe the volume of post-service cases that otherwise qualify under the requirements for an expedited integrated organization determination would be high, so we do not expect this to be a burden to D–SNPs that would be required to comply with unified appeals requirements we propose here. There may be circumstances in which an enrollee's financial need is particularly pressing. Accordingly, in § 422.633(f)(1), we propose to require that all integrated reconsiderations be resolved within 30 calendar days of receipt similar to the Medicaid managed care regulations. We considered applying the approach taken in the MA regulations that gives MA plans more time to resolve post-service payment cases so that plans can prioritize cases where an enrollee is waiting for a service to start or an item to be provided. However, given the financial circumstances of enrollees in applicable integrated plans, we propose requiring the same resolution timeframe for all integrated reconsideration to ensure prompt repayment. We invite comments on this proposal—both on the overall 30 calendar day period and on permitting expedited post-service integrated reconsideration—as we recognize this would constitute a change to current D–SNP operations.

In paragraph (f)(2), we propose to establish the timeframes for expedited reconsiderations. Both MA (at § 422.590(d)(1)) and Medicaid (at § 438.408(b)(3)) allow 72 hours for resolution of an expedited reconsideration or appeal. We propose to adopt the same rule for integrated reconsiderations. We also propose to apply the Medicaid managed care requirement (at § 438.408(d)(2)(ii)) by requiring that applicable integrated plans make reasonable efforts to give enrollees oral notice of the resolution in expedited cases, in addition to sending the written notice within 72 hours of receipt of the request.

In paragraph (f)(3)(i), we propose criteria for an applicable integrated plan to extend the timeframe for resolving either a standard or expedited reconsideration. MA (at § 422.590(e)) and Medicaid (at § 438.408(c)) have similar rules, both allowing 14-day extensions upon request of the enrollee (or the enrollee's representative) and when the plan can demonstrate an extension is in the enrollee's interest. We propose to adopt a similar standard here, generally using the standard in § 438.408(c) that the plan must show that the extension is in the enrollee's interest and that the information is necessary. We also propose to use the MA standard that the timeframe may be extended if there is a need for additional information and there is a reasonable likelihood that receipt of such information would lead to approval of the request, as this standard is more protective of the enrollee. Using this standard, an applicable integrated plan would be prohibited from extending the deadline for its integrated reconsideration in order to gather information to justify continuing its original denial of coverage. We request comments regarding whether additional specificity is needed.

In paragraph (f)(3)(ii), we propose requirements for the notice that applicable integrated plans must send to enrollees when the plan extends the timeframe for making its determination, in accordance with the requirements in this paragraph. We propose to require that the applicable integrated plan make reasonable efforts to give the enrollee prompt oral notice and give the enrollee written notice within 2 calendar days. These requirements align with current Medicaid managed care regulations at § 438.408(c)(2). The MA regulation requires that the plan notify the enrollee in writing as expeditiously as the enrollee's health condition requires, but no later than the expiration of the extension period (§ 422.590(e)(2)). We find the Medicaid managed care requirements to be more protective to enrollees since they are likely to provide faster notice to the enrollee of the determination. We also propose that the notice of the extension include the reason for the delay and inform the enrollee of the right to file an expedited grievance if the enrollee disagrees with the decision to extend the timeframe. Both Medicaid managed care and MA require similar information. However, only MA requires information on an expedited grievance process, since only MA includes an expedited grievance process. Since we are proposing to include an expedited grievance process, we are proposing to require information about that process in this notice.

In paragraph (f)(4), we propose requirements for providing appellants with notices regarding the resolution of reconsiderations. We propose to require that applicable integrated plans send notices within the resolution timeframes established in this section for all integrated reconsideration determinations. Medicaid managed care regulations require notices of all determinations. MA regulations will no longer, effective for the 2019 plan year, require MA plans to send written determinations in cases where the determination is fully or partially unfavorable to the enrollee because MA enrollees will still receive a notice from the independent entity once the MA plan forwards the case for fully or partially unfavorable determinations (see 83 FR 16634 through 16635). We believe that requiring applicable integrated plans to send notices for all integrated reconsideration determinations is in line with the principles identified in section 1859(f)(8)(B) of the Act for a unified process, and timely, clear notification for enrollees. We also propose to include language requiring that the notice be written in plain language and available in a language and format that is accessible to the enrollee consistent with section 1859(8)(B)(iii)(III) of the Act. We also propose, in paragraphs (f)(4)(i) and (ii), to adopt the standards similar to those governing the content of a notice found in § 438.408(e)—namely, that the plan must provide a notice of the integrated reconsideration for an adverse decision that includes the reason for the decision and the date of completion. We propose in paragraph (f)(4)(ii)(A) that, for integrated notices not resolved wholly in the enrollee's favor, the notice include an explanation

of the next level of appeal under both Medicare and Medicaid, and what steps the enrollee must take to further pursue the appeal. Our expectation is that the integrated notice will enable the enrollee to understand which program covers the benefit at issue. We also propose in paragraph (f)(4)(ii)(B) that the notice include specific information about the ability to request continuation of Medicaid-covered benefits pending appeal.

(9) Effect (§ 422.634)

We propose, at § 422.634(a), to use the same standard as in existing MA and Medicaid regulations related to a plan's failure to made a timely determination. If an applicable integrated plan fails to make a timely determination at any point in the appeals process (for an integrated organizational determination or an integrated reconsideration), that failure would constitute an adverse determination, such that the enrollee could move forward with the next level of appeal procedures (see §§ 438.400(b)((b), 438.402(c)(1)(i)(A), 438.408(c)(3), 422.568(f), and 422.572(f)).

We propose, at § 422.634(b), to establish the next steps in the appeals process if the enrollee receives an adverse decision from the applicable integrated plan on the integrated reconsideration. For cases involving Medicare benefits, we propose, for applicable integrated plans at § 422.634(b)(1)(i), the same processes as currently exist in MA at § 422.590(a)(2) and (d)(4) for forwarding the case file and timing. In § 422.634(b)(1)(ii) and (iii), we propose to mirror the MA regulations (§ 422.590(a)(2) and (d)(3)) with requirements for applicable integrated plans to forward the case file to the independent entity.

At § 422.634(b)(2), we propose that for cases involving Medicaid benefits, the enrollee may initiate a state fair hearing no later than 120 calendar days from the date of the applicable integrated plan's notice of resolution. This proposal would, in effect, impose the same process on appeals from integrated reconsiderations related to Medicaid coverage as applies under § 438.408(f)(2) and (3). We also propose to include the requirement that a provider who has not already obtained the written consent of an enrollee must do so before filing a request for a state fair hearing, in accordance with existing Medicaid requirements, since our proposed regulations would only apply new processes and requirements through the integrated reconsideration.

We also propose to parallel, at proposed § 422.634(c), MA regulation language at § 422.576 clarifying that determinations are binding on all parties unless the case is appealed to the next applicable level of appeal. We also propose to specify that this means that, in the event that an enrollee pursues an appeal in multiple forums simultaneously (for example, files for an external state medical review and an integrated reconsideration with the applicable integrated plan, and the integrated reconsideration decision is not in the enrollee's favor but the external state medical review decision is), an applicable integrated plan would be bound by, and must implement, decisions favorable to the enrollee from state fair hearings, external medical reviews, and independent review entities (IRE).

We propose, at § 422.634(d), to parallel Medicaid requirements, from § 438.424(a), detailing how quickly services must be put in to place for an enrollee after he or she receives a favorable decision on an integrated reconsideration or state fair hearing. We propose to include the current Medicaid managed care requirement that, if a decision is favorable to the enrollee, the applicable integrated plan must authorize or provide the disputed benefit as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination. MA's rule for effectuation of a standard organization determination at § 422.618(a) also requires effectuation as expeditiously as the enrollee's health requires, but allows a maximum of 30 days. We believe the shorter, 72-hour maximum is more protective of the needs of dually eligible beneficiaries. We also note that a 72-hour effectuation period is the same as Medicare's timeframe for an expedited determination at § 422.619(a), so that plans should be accustomed to effectuating decisions under this timeframe. Finally, we also propose in this paragraph to maintain the same effectuation timelines for reversals by the Medicare independent review entity as apply to other MA plans.

We propose, at § 422.634(e), for Medicaid-covered benefits, to parallel Medicaid requirements from § 438.424(b) governing how services that were continued during the appeal must be paid for, if the final determination in the case is a decision to deny authorization of the services. For Medicare-covered services, we propose that the applicable integrated plan will cover the cost of the benefit.

(10) Unifying Medicare and Medicaid Appeals Subsequent to Integrated Reconsideration

The new section 1859(f)(8)(B)(ii) of the Act directs us to include, to the extent we determine feasible, consolidated access to external review under an integrated process. We interpret ''external review'' in this statutory provision as meaning review outside the plan, including by a government agency or its designee. For MA, this includes the independent review entity (IRE) and ALJ review described in §§ 422.592 through 422.602. For Medicaid, this includes the state fair hearing process described in Part 431 Subpart E, as well as any additional external review offered under state law.

A unified and integrated appeals process subsequent to a plan decision could be significantly simpler for beneficiaries to navigate, as they would not have to determine whether they should be pursuing a Medicare appeal, a Medicaid appeal, or both. Such a process could reduce burden for plans, states, and the federal government by reducing the number of duplicative appeals. However, unifying D–SNP and Medicaid appeals subsequent to the reconsideration level also presents considerable challenges. Currently, once a D–SNP or Medicaid managed care plan makes a final decision on an appeal, the federally-administered Medicare and state-administered Medicaid appeals processes are entirely separate. Although they have some common principles, such as ensuring access to an independent administrative hearing, they differ in many respects. Specific differences include:

- Reconsideration by an independent entity: Section 1852(g)(4) of the Act, which is implemented in MA rules at §§ 422.592 through 422.596, requires that all adverse plan appeal decisions be reviewed by an independent entity. Under the regulations, this review is on the record and happens automatically for Part C claims, as the MA plan is required to forward any adverse reconsideration to the IRE. This IRE review takes place before a beneficiary can request an administrative hearing before an administrative law judge but, because each adverse reconsidered determination is automatically forwarded to the IRE, the enrollee is not required to initiate these reviews. In the Medicaid managed care context, there is no federal regulation or statute that similarly requires a review by an external entity before access to a governmental review; pursuant to §§ 438.402(c)(1)(i)(B) and

438.408(f)(1)(ii), a state may make a voluntary external medical review process available to enrollees in a Medicaid managed care plan so long as the process does not interfere with enrollees' right to proceed to a state fair hearing.

- Immediate access to an administrative hearing: The applicable Medicaid managed care program regulations (§§ 438.402(c)(1)(i)(B) and 438.408(f)) specify that any external review cannot be required before allowing a beneficiary to proceed to the state fair hearing, so that the state fair hearing process is available immediately following the Medicaid managed care plan's appeal determination if the enrollee elects.
- Amount in controversy: Section 1852(g)(5) of the Act requires that an amount in controversy be met for a hearing before the Secretary on appeal and for judicial review. In 2018, those thresholds are $160 for an Administrative Law Judge hearing and $1,600 for judicial review.[17] Medicaid has no similar provision.
- Reviewing agency and subsequent review: Medicaid program rules at Part 431 Subpart E (which are not limited to Medicaid managed care plans but also control appeals in the Medicaid fee-for-service context) require that beneficiaries always have the right to request a hearing before the state agency for a review of a denial of service (§ 431.205(b)(1)) or for a reduction, termination, or reason described at § 431.220(a). Medicaid hearings are held by the state Medicaid agency or, in limited circumstances, its designee. Subsequent review procedures vary based on state law. Section 1852(g)(5) of the Act provides that a MA enrollee is entitled, if the amount in controversy threshold is met, to a hearing before the Secretary to the same extent as is provided in section 205(b) of the Act. The MA regulations (at §§ 422.562(b)(4)(iv)–(vi) and (d), and §§ 422.600 through 422.616) implement this requirement by providing for appeals to be made to the Office of Medicare Hearings and Appeals and Medicare Appeals Council using substantially the same procedures and processes used for appeals of claims denials under Part A and Part B of Medicare.
- *Timelines and procedural rules:* Medicaid's procedural rules on matters such as timelines and location of a hearing vary by state and may differ from the rules applicable to MA. For example, Medicaid rules at § 431.224 allow for expedited fair hearing hearings under certain circumstances, whereas there is no equivalent expedited hearing process at the Medicare ALJ level for Part C/MA appeals.

In addition, our authority to unify appeals procedures under Medicare and Medicaid and to provide consolidated access to external review under section 1859(f)(8)(B) of the Act cannot be used to diminish any appeal rights under Medicare or Medicaid. In the context of establishing the unified procedures for appeals and grievances, the statute provides authority to waive only section 1852(g)(1)(B) of the Act (which imposes certain notice requirements for MA organizations) and directs unification—rather than amendment or elimination—of procedures under sections 1852(f), 1852(g), 1902(a)(3), 1902(a)(5), and 1932(b)(4) of the Act. In many ways, those statutory provisions do not direct specific procedures but provide some measure of discretion in effectuating appeal rights. But where those statutory provisions are specific, we generally do not have authority under section 1859(f)(8)(B) of the Act to waive the specific requirements in establishing unified procedures and processes. In addition to the statutory differences we have already outlined earlier, section 1852(g)(5) of the Act providing Medicare beneficiaries with an opportunity for a hearing before the Secretary, and the analogous provision at section 1902(a)(3) of the Act providing Medicaid beneficiaries with a hearing before the state Medicaid agency, are rights that must be met and present challenges in establishing a consolidated, unified, post-plan appeals process. We believe that a state-level unified appeals process to adjudicate both Medicare and Medicaid claims would satisfy section 1902(a)(3) of the Act in providing Medicaid beneficiaries with access to a state fair hearing. However, to comply with section 1852(g)(5) of the Act, such a system would need to include a pathway for a federal review of Medicare claims, in a manner that provides a hearing before the Secretary. Conversely, a federal-level unified appeals process would satisfy section 1852(g)(5) of the Act but would need to include a pathway for an enrollee to elect additional state agency review of Medicaid claims. Finally, we believe as a practical matter that any entity adjudicating cases in a unified process outside its traditional jurisdiction (that is, a state entity reviewing Medicare claims or a federal entity reviewing Medicaid claims) should be subject to some additional review to ensure that its decisions were consistent with the applicable law (that is, federal Medicare and state Medicaid criteria for benefits coverage).

Based on these complexities, we believe it is not feasible to propose a unified post-plan appeals process (that is, adjudication of appeal subsequent to an applicable integrated plan's integrated reconsideration of an initial adverse determination) at this time. Instead we ask for comments on viable paths forward given the constraints presented by the statutory mandates for the MA and Medicaid appeals processes and our experience gained through demonstrations. We hope to propose the establishment of a unified post-plan appeals process in a future rulemaking, based on comments from this request for information and additional experience. We discuss our experiences and key areas for comment below.

Our sole experience with a unified appeals process subsequent to the plan's final reconsideration of an initial benefit denial operates under demonstration authority at the state level through a partnership between CMS and the state of New York as part of the Financial Alignment Initiative capitated model demonstrations. The New York Financial Alignment Initiative demonstration, called Fully Integrated Duals Advantage (FIDA), includes a fully integrated appeals process for appeals from Medicare-Medicaid Plans (MMPs) authorized under section 1115A waiver authority.[18] We note that this model was established under demonstration authority prior to enactment of section 1859(f)(B)(8) of the Act, and some aspects of the model may not be fully consistent with the provisions of Titles XVIII and XIX as they would operate under a unified process implemented under the new statute. In the FIDA integrated process, all adverse decisions by FIDA MMPs, regardless of amount in controversy, are automatically forwarded to a specialized unit of the New York administrative hearing agency that conducts state Medicaid fair hearings. This specialized unit has staff trained in both Medicare and Medicaid coverage rules, schedules each denial for a hearing, and applies both Medicare and Medicaid coverage criteria in reviewing the decision. Decisions affirming an MMP's denial may be appealed to the federal Departmental Appeals Board's Medicare Appeals Council, thereby ensuring an

[17] 82 FR 45592 (September 29, 2017).

[18] Section 2.13 of the FIDA contract, available at *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/NYFIDAContract01012018.pdf.*

opportunity for federal review of Medicare claims.

Our experience with the New York FIDA unified appeals process suggests that any procedures we establish for a unified post-plan appeals process should be available as an option for states to implement in partnership with CMS, rather than a nationwide requirement. The New York FIDA experience has taught us that operating a unified process requires considerable commitment, planning, and coordination by both CMS and the state Medicaid agency, as well as from other agencies that are part of the administrative hearing and review process for Medicare and Medicaid (in this case, the New York state hearing agency and the federal Departmental Appeals Board (DAB)). Although models other than the New York FIDA model are feasible, any unified adjudication entity for D–SNP appeals subsequent to the plan's reconsideration would need to administer its own procedures and be familiar with the substance of both Medicare and state-specific Medicaid coverage rules. Given the resources and commitment needed, we anticipate that only a limited number of states would wish to pursue a unified system with CMS for appeals processes following the decisions by applicable integrated plans. In addition, based on our experience with the Financial Alignment Initiative demonstrations in other states, we believe an appeals system that is integrated at the plan level but which diverges subsequently can also be effective at ensuring appropriate review of plan decisions. Therefore, we believe that mandating a unified process subsequent to reconsideration for all states would be unwise and likely infeasible.

We also believe that any post-plan appeals process should be limited to appeals of decisions made by applicable integrated plans as we propose to define them in § 422.561. We believe the integrated organization determination and integrated reconsideration processes we propose in §§ 422.631 and 422.633 lend themselves to an integrated post-plan appeals process much more than a system that attempts to integrate appeals made by separate MA and Medicaid managed care plans.

Any regulation to establish a post-plan unified appeals process would need to address the following misalignments in particular:

• *Harmonizing the Medicare Advantage requirement for an external independent review with Medicaid's prohibition on additional levels of administrative review between a plan decision and a state fair hearing:* The approaches to post-plan review do not align neatly across Medicare Advantage and Medicaid managed care. Section 1852(g)(4) of the Act (governing Medicare Advantage appeals processes) requires that CMS contract with an independent external entity to conduct an external review of all adverse reconsiderations. CMS has implemented this provision at § 422.592 by requiring an automatic referral of adverse plan reconsiderations to the IRE for an administrative review. In the appeals structure for Medicaid managed care plans, a plan's adverse action is not reviewed automatically, but beneficiaries may request a fair hearing before the state Medicaid agency (or, in limited cases, its designee) immediately following a plan's decision, under procedures described in Part 431 Subpart E. Requiring an additional level of external review for all integrated appeals prior to allowing a state fair hearing would be inconsistent with Medicaid policy, as we have only permitted establishment of external medical reviews for Medicaid managed care plans if such reviews do not impede access to a state fair hearing (see, for example, § 438.408(f)(1)(ii) and discussion at 81 FR 27518 (May 6, 2016)). We are concerned that having a requirement for external review of all adverse integrated reconsiderations before access to the state fair hearing would impede dually eligible beneficiaries' timely access to a fair hearing. However, allowing beneficiaries to proceed directly to a governmental hearing to address Medicare-related issues without prior external review could be inconsistent with the MA statutory requirement for independent, external review. Furthermore, if the review, be it external or by state fair hearing, were not automatic, then an adverse reconsideration might not be reviewed at all, which would be inconsistent with protection provided by the automatic referral in § 422.592. We do not believe either a purely Medicare-based or Medicaid-based procedure is desirable in a unified post-plan appeals process.

We have considered one approach that could accommodate these constraints. Under this potential approach, a state entity with expertise in both Medicare and Medicaid coverage rules would review all adverse integrated reconsiderations issued by the plan. This entity would conduct its review in the form of an automatic state fair hearing consistent with Medicaid hearing procedures (such as the opportunity to present evidence), as is done in the New York FIDA demonstration. The automatic fair hearing would also constitute the independent external review required by section 1852(g)(4) of the Act. In order to comply with the statute, CMS and the state entity would have to enter into a contract to perform the independent review. Following this state fair hearing, appeals regarding Medicare-related issues would be subject to additional appeal rights, but as we discuss below, operationalizing those rights presents challenges as well.

We invite comments on the feasibility and desirability of this approach. We are particularly interested in whether there are instructive analogous examples of state-federal contracting that successfully demonstrate states performing a task subject to federal oversight. We also seek input regarding any advantages and disadvantages to providing the automatic review in the form of a state fair hearing. Finally, we welcome suggestions for alternative models that could harmonize the MA and Medicaid managed care requirements while maintaining compliance with all statutory provisions.

• *Preserving the right to hearing before the Secretary:* Section 1852(g)(5) of the Act requires the opportunity for Medicare beneficiaries to have a hearing before the Secretary when an amount in controversy threshold is met. In order to preserve that right, a unified process would need to allow a beneficiary whose appeal is unsuccessful at the independent review level to request a hearing before the Secretary (presumably through the Office of Medicare Hearings and Appeals (OMHA)) when an appeal involves a Medicare item or service (meaning a Part A benefit, Part B benefit, or supplemental benefit offered under the Medicare Advantage contract) meeting the amount in controversy threshold. But this appeal level would not be available for appeals of Medicaid-based cases or for Medicare cases not meeting the amount in controversy. In effect, this would mean beneficiaries would need to split their cases into separate Medicare and Medicaid pathways if they wished to seek a hearing before the Secretary for their Medicare claims meeting the amount in controversy. In addition, it would essentially create the possibility for two hearings: First an automatic integrated independent review and fair hearing at a state-level integrated entity, followed by an optional Medicare-only hearing at OMHA for Medicare matters meeting the amount in controversy threshold. Although such a process could be

operationalized, we believe it might also be confusing to beneficiaries and inconsistent with the goal of a simpler unified appeals process. We therefore seek comments how best to preserve beneficiaries' rights under section 1852(g)(5) of the Act and simultaneously establish a unified process.

• *Pathways for subsequent review:* We seek input on the related question of how to structure other forms of subsequent review for a unified post-plan appeal. Any unified procedure must preserve both state-specific avenues for further review of Medicaid-related fair hearing decisions (for example, additional administrative review and state court review) and ensure that Medicare-related decisions are reviewable consistent with section 1852(g)(5) of the Act (for example, review by the Medicare Appeals Council and federal judicial review under certain circumstances). We believe that maintaining all these routes of appeal would mean that a unified case would eventually have to be separated into Medicaid and Medicare components, which could be difficult for beneficiaries and plans to navigate. We invite comments regarding how to approach this problem. We are considering providing state Medicaid agencies with the authority to delegate review of a state fair hearing decision to a federal entity (at state option and only with the federal entity's consent) in order to keep the unified appeal together. This is the approach in the New York FIDA demonstration, where the Medicare Appeals Council can review Medicaid aspects of a FIDA decision. Such an approach may be technically feasible, but we seek input regarding the advantages and disadvantages of such a delegation.

• *Specificity of rulemaking:* Depending on the resolution of these issues in developing a unified post-plan appeals process, additional federal rulemaking is likely to be necessary to amend or create exceptions to the current MA requirements for IRE review and the governmental administrative appeals process (see §§ 422.592 through 422.619). In addition to statutory requirements for rulemaking (for example, the Administrative Procedure Act and section 1871 of the Act), it would also be necessary to ensure that all stakeholders have an opportunity to review and comment on the proposal. However, establishing a specific process in federal regulation constrains our ability to accommodate state-specific flexibility. Some flexibility is possible: For example, timelines for review by an independent entity are not established by Medicare regulation. Timelines for a unified independent review and fair hearing could therefore also vary by state to reflect state-specific fair hearing rules. But any substantial variation that affected appeal rights for MA (specifically D–SNP) enrollees might be subject to additional federal rulemaking. For example, a model that would limit unified post-plan appeals to only certain benefits (for example, services like home health and durable medical equipment where Medicare and Medicaid have differing coverage rules), would be subject to additional rulemaking. We seek comment regarding what aspects of a unified post-plan appeals process would necessitate state-specific flexibility, including discussion of whether any of those aspects would implicate rights under MA statute or would otherwise necessitate additional federal rulemaking.

In summary, we believe that establishment of a unified post-plan appeals process may be feasible in the future if we can address these issues, and we believe that such a process could offer benefits to beneficiaries, plans, states, and the federal government. We welcome feedback from all stakeholders on the issues raised earlier, as well as any others pertaining to a post-plan appeals process.

(11) Conforming Changes to Medicare Managed Care Regulations and Medicaid Fair Hearing Regulations (§ 422.562, § 422.566, § 438.210, § 438.400, and § 438.402)

We propose a number of changes to Medicaid managed care, Medicaid fair hearing, and Medicaid single state agency regulations to conform with our proposed unified grievance and appeals provisions. Following is a summary of these proposed changes.

• In § 422.562(a)(1)(i) and (b), we propose to add cross references to the proposed integrated grievance and appeals regulations along with new text describing how the provisions proposed in this rule for applicable integrated plans would apply in place of existing regulations.

• In § 422.566, we propose to add additional language to paragraph (a) to establish that the procedures we propose in this rule governing integrated organization determinations and integrated reconsiderations at proposed § 422.629 through § 422.634 apply to applicable integrated plans in lieu of the procedures at §§ 422.568, 422.570, and 422.572.

• In § 438.210(c) and (d), we propose to add cross references to the proposed integrated grievance and appeals regulations along with new text describing how the provisions proposed in this rule for applicable integrated plans would apply in place of existing regulations to determinations affecting dually eligible individuals who are also enrolled in a D–SNP with exclusively aligned enrollment, as those terms are defined in § 422.2. In § 438.210(f), we propose to make these Medicaid changes applicable to applicable integrated plans no later than January 1, 2021, but, consistent with our discussion earlier on the effective dates of our proposed unified appeals and grievance procedures overall, we would not preclude states from applying them sooner.

• In § 438.400, we propose adding a new paragraph (a)(4) to include the statutory basis for the proposed integration regulations (section 1859(f)(8) of the Act). We also propose to amend § 438.400(c) to clarify that these Medicaid changes apply to applicable integrated plans no later than January 1, 2021, but, consistent with our discussion earlier on the effective dates of this rule overall, we would not preclude states from applying them sooner.

• In § 438.402, we propose amending paragraph (a) to allow a Medicaid managed care plan operating as part of an applicable integrated plan to the grievance and appeal requirements laid out in §§ 422.629 through 422.634 in lieu of the normally applicable Medicaid managed care requirements.

3. Proposal for Prescription Drug Plan Sponsors' Access to Medicare Parts A and B Claims Data Extracts (§ 423.153)

a. Background

This proposed rule sets forth the manner in which CMS proposes to implement section 50354 of the Bipartisan Budget Act of 2018 (BBA), Public Law 115–123, enacted on February 9, 2018. Section 50354 amends section 1860D–4(c) of the Social Security Act by adding a new paragraph (6) entitled ''*Providing Prescription Drug Plans with Parts A and B Claims Data to Promote the Appropriate Use of Medications and Improve Health Outcomes*''. Specifically, section 1860D–4(c)(6)(A), as added by section 50354 of the BBA, provides that the Secretary shall establish a process under which the sponsor of a Prescription Drug Plan (PDP) that provides prescription drug benefits under Medicare Part D may request, beginning in plan year 2020, that the Secretary provide on a periodic basis and in an electronic format standardized extracts of Medicare claims data about its plan

enrollees. Such extracts would contain a subset of Medicare Parts A and B claims data as determined by the Secretary. In defining the specific data elements and time frames for the Parts A and B claims data included in such extracts, hereinafter referred to as ''Medicare claims data,'' the Secretary is instructed, at section 1860D–(4)(c)(6)(D) of the Social Security Act, to include data ''as current as practicable.''

Section 1860D–4(c)(6)(B), as added by section 50354 of the BBA, further specifies that PDP sponsors receiving such Medicare claims data for their corresponding PDP plan enrollees may use the data for: (i) Optimizing therapeutic outcomes through improved medication use; (ii) improving care coordination so as to prevent adverse healthcare outcomes, such as preventable emergency department visits and hospital readmissions; and (iii) for any other purposes determined appropriate by the Secretary. Finally, section 1860D–4(c)(6)(C) states that the PDP sponsor may not use the data: (i) To inform coverage determinations under Part D; (ii) to conduct retroactive reviews of medically accepted conditions; (iii) to facilitate enrollment changes to a different PDP or a MA–PD plan offered by the same parent organization; (iv) to inform marketing of benefits; and (v) for any other purpose the Secretary determines is necessary to include in order to protect the identity of individuals entitled to or enrolled in Medicare, and to protect the security of personal health information.

b. Provisions of the Proposed Rule

To implement the new statutory provision at section 1860D–4(c)(6), as added by section 50354 of the BBA, we propose to add a new paragraph (g) at § 423.153. Throughout this discussion of our proposed approach, we identify options and alternatives to the policies we propose. We strongly encourage comments on our proposed approach, as well as any alternatives.

c. Purposes and Limitations on the Use of Data

Section 1860D–4(c)(6)(B) of the Act expressly permits the use of Medicare claims data for two specified purposes: (1) To optimize therapeutic outcomes through improved medication use and (2) to improve care coordination so as to prevent adverse health outcomes. In addition, section 1860D–4(c)(6)(B)(iii) provides that the Secretary can determine if there are other appropriate purposes for which the data may be used.

Therefore, consistent with the statute, we propose at § 423.153(g)(3), that PDP sponsors would be permitted to use Medicare claims data to optimize therapeutic outcomes through improved medication use, and to improve care coordination so as to prevent adverse health outcomes. In addition, we propose to permit PDP sponsors to use Medicare claims data for the purposes described in the first or second paragraph of ''health care operations'' under 45 CFR 164.501, or that qualify as ''fraud and abuse detection or compliance activities'' under 45 CFR 164.506(c)(4). We also propose to permit disclosures that qualify as a ''required by law'' disclosure as defined at 45 CFR 164.103. We believe these uses should encompass the full range of activities for which the PDP sponsors will need Medicare claims data. However, we request comments on whether there are any additional purposes for which PDP sponsors should be permitted to use Medicare claims data provided under this subsection.

Section 1860D–4(c)(6)(C) of the Act places specific limitations on how Medicare claims data provided to the PDP sponsors may be used and also permits the Secretary to determine if any additional limitations should be imposed to protect the identity of individuals entitled to, or enrolled for, benefits under Medicare and to protect the security of personal health information. Therefore, consistent with these statutory limitations, at § 423.153(g)(4), we propose that PDP sponsors must not use Medicare claims data provided by CMS under this subsection for any of the following purposes: (i) To inform coverage determinations under Part D; (ii) To conduct retroactive reviews of medically accepted indications determinations; (iii) To facilitate enrollment changes to a different prescription drug plan or an MA–PD plan offered by the same parent organization; and/or (iv) to inform marketing of benefits.

Section 1860D–4(c)(6)(C)(v) of the Act provides that the Secretary may place additional limitations on the use of Medicare claims data as necessary to protect the identity of individuals entitled to, or enrolled for, benefits under Part D, and to protect the security of personal health information. CMS is committed to ensuring beneficiary-level data is protected by strict privacy and security requirements. Therefore, at § 423.153(g)(4)(v), we also propose to require that the PDP sponsor contractually bind its Contractors that it anticipates giving access to Medicare claims data, and any other potential downstream data recipients, to the terms and conditions imposed on the PDP Sponsor under the proposed provision at § 423.153(g). In addition, we propose at § 423.153(g)(4)(vi) that CMS may refuse to make future releases of Medicare claims data to the PDP sponsor if it makes a determination or has a reasonable belief that unauthorized uses, reuses, or disclosures have taken place.

We believe that PDP sponsors are business associates receiving Medicare claims data on behalf of the PDP, a health plan and HIPAA covered entity. We also believe that Medicare claims data provided to PDP sponsors under § 423.153(g) is protected health information (PHI). As a business associate, the PDP sponsor is required to comply with the HIPAA Rules, including Privacy, Security and Breach Notification requirements for PHI. Therefore, we do not propose any additional limitations on the PDP sponsors' use of the Medicare claims data. However, we request comments on whether there are any additional limitations that should be placed on Medicare claims data provided under § 423.153(g). To ensure that the PDP sponsors understand the purposes for which the Medicare claims data may be used and the limitations on its use, we propose at § 423.153(g)(5)) to require that, as a condition of receiving the requested data, the PDP sponsor must attest that it will adhere to the permitted uses and limitations on the use of the Medicare claims data in paragraphs (3) and (4) of § 423.153(g). We propose to require this attestation as a means of ensuring an understanding of, and compliance with, the terms and conditions of data access. We believe that our proposal to require PDP sponsors to attest that they will comply with these requirements is necessary to ensure the protection of the identities of Medicare beneficiaries and the security of the Medicare claims data. We request comments on our proposal to require PDP sponsors to submit an attestation and on the specific requirements that should be included in that attestation.

d. Data Request

Section 1860D–4(c)(6)(A) of the Act provides that the Secretary shall establish a process under which a PDP sponsor of a prescription drug plan may submit a request for the Secretary to provide the sponsor with standardized extracts of Medicare claims data for its enrollees. Therefore, we propose at § 423.153(g)(1) to establish a process by which a PDP sponsor may submit a request to CMS to receive standardized extracts of Medicare claims data for its enrollees. We propose to accept data requests on an ongoing basis beginning

January 1, 2020. We propose to require that such data requests must be submitted in a form and manner specified by CMS. Consistent with the discretion accorded to the Secretary under section 1860D–4(c)(6)(D) of the Act, we propose not to allow PDP sponsors to request data for subsets of their enrolled beneficiary populations. We propose allowing requests to be submitted without an end date, such that the request, once reviewed for completeness and approved, will remain in effect until one or more of the following occur: The PDP sponsor notifies CMS that it no longer wants to receive Medicare claims data, CMS cancels access to Medicare claims data when a PDP sponsor leaves the Part D program, or CMS concludes or has a reasonable belief, at its sole discretion, that the PDP sponsor has used, reused or disclosed the Medicare claims data in a manner that violates the requirements of section 1860D–4(c)(6) and § 425.153(g) of the Act. Upon receipt of the request from the PDP sponsor and the PDP's execution of an attestation discussed earlier, and review for completeness and approval of the application by CMS or its contractor, we propose that the PDP sponsor would be provided access to Medicare claims data. We note that access to Medicare claims data will be further subject to all other applicable laws, including, but not limited to, the part 2 regulations governing access to certain substance abuse records (42 CFR part 2).

d. Data Extract Content

To develop a proposed data set to include in the standardized extracts of Medicare claims data, we first considered what Medicare claims data PDP sponsors might require if they were to undertake the activities expressly permitted by section 1860D–4(c)(6)(B) of the Act. In doing so, we attempted to limit the data set to the minimum data that we believe PDP sponsors would need to carry out those statutory activities and the additional activities we are proposing to permit under § 423.153(g)(3). That is, we sought to establish data access limits that would comport with the HIPAA Privacy Rule's minimum necessary concept at 45 CFR 164.502(b) and 164.514(d), and CMS' policy-driven data release policies.

We believe that data from all seven claim types, including inpatient, outpatient, carrier, durable medical equipment, hospice, home health, and skilled nursing facility data, would be required to carry out the permitted uses of the data under section 1860D–4(c)(6)(B) and the proposed provision at § 423.153(g)(3). We believe that information on all Parts A and B services provided to a patient, as well as the dates on which those services were furnished, would provide a more complete picture of a patient's health care services and support care coordination and quality improvement activities. In addition, this claims information would provide insight into the services or procedures that resulted in a patient receiving a certain prescription drug, and the particular care setting in which the drug was prescribed, which will assist PDP sponsors in promoting the appropriate use of medication and improving health outcomes for their enrollees.

We also considered the types of data elements that other entities request when they ask for data to conduct care coordination and quality improvement work. For example, we looked at the data elements requested by entities participating in the CMS Oncology Care Model (OCM). OCM aims to provide higher quality, more highly coordinated oncology care at the same or lower cost to Medicare. Because Section 1860D–4(c)(6) focuses on providing Medicare claims data to promote the appropriate use of medications and improve health outcomes, we propose to initially include the following Medicare Parts A and B claims data elements (fields) in the standardized extract: An enrollee identifier, diagnosis and procedure codes (for example, ICD–10 diagnosis and Healthcare Common Procedure Coding System (HCPCS) codes); dates of service; place of service; provider numbers (for example, NPI); and claim processing and linking identifiers/codes (for example, claim ID, and claim type code). CMS will continue to evaluate the data elements provided to PDP sponsors to determine if data elements should be added or removed based on the information needed to carry out the permitted uses of the data. In making decisions about adding data elements to the standardized extracts, CMS will consider whether the additional data elements support the purposes for which the data can be used. Any proposed changes would be established through rulemaking.

We next considered the beneficiary population for which we should draw the identified data elements, and what time span of data would best serve PDP sponsors while honoring the requirement at section 1860D–4(c)(6)(D) of the Act that the data should be as current as practicable. Taking into account the purpose for which Medicare claims data is being provided, namely to support the appropriate use of medications and improve health outcomes, we believe that only the most current data is relevant. Therefore, because only the most timely data is needed for care coordination purposes, we propose at § 423.153(g)(2) to draw the standardized extracts of Medicare claims data for items and services furnished under Medicare Parts A and B to beneficiaries who are enrolled in a Part D plan offered by the Part D sponsor at the time of the disclosure. We anticipate that Medicare claims data would be provided at least quarterly with approximately a 3 month lag from the last day of the last month of the prior quarter. In addition, we anticipate it can take up to two months to process and ship the data extracts from the date the quarterly data is available. Therefore, we propose that the first standardized data extract would be available to PDP sponsors no earlier than August 15, 2020, which would include, at a minimum, data for the period beginning January 1, 2020, and ending on March 1, 2020. In addition, given the permitted uses of the data, we propose to use a standard format to deliver the resulting data to each PDP sponsor with standard format extracts, meaning that CMS would not customize the extracts for a PDP sponsor. We propose to make these standardized data extracts available to eligible PDP sponsors at least quarterly, as described earlier, but only on a specified release date that would be applicable to all eligible PDP Sponsors. That is, we propose that newly eligible PDP sponsors would not have an opportunity to request standardized data extracts generated retroactively after the passing of the release date for a given release. Therefore, if a PDP sponsor submits a request, is approved to receive data, and executes its attestation after the release of a set of data extracts (for example, after the release date for Quarter 1 2020), we anticipate that the newly eligible PDP Sponsor would not receive data until the next standardized data extract is available (for example, the release date for Quarter 2 of 2020).

We believe that these standardized data extracts would provide PDP sponsors with the minimum data necessary to carry out the permitted uses specified in section 1860D–4(c)(6)(B) of the Act and as proposed at § 423.153(g)(3). We seek comments about the proposed frequency and contents of the standardized data extracts.

B. Improving Program Quality and Accessibility

1. Medicare Advantage and Part D Prescription Drug Plan Quality Rating System (§§ 422.162(a) and 423.182(a), §§ 422.166(a) and 423.186(a), §§ 422.164 and 423.184, and §§ 422.166(i)(1) and 423.186(i)(1))

a. Introduction

Earlier this year, in the April 2018 final rule, CMS codified at §§ 422.160, 422.162, 422.164, and 422.166 (83 FR 16725 through 83 FR 16731) and §§ 423.180, 423.182, 423.184, and 423.186 (83 FR 16743 through 83 FR 16749) the methodology for the Star Ratings system for the MA and Part D programs, respectively. This was part of the Administration's effort to increase transparency and advance notice regarding enhancements to the Part C and D Star Ratings program. Going forward CMS must propose through rulemaking any changes to the methodology for calculating the ratings, the addition of new measures, and substantive measure changes. The April 2018 final rule included mechanisms for the removal of measures for specific reasons (low statistical reliability and when the clinical guidelines associated with the specifications of measures change such that the specifications are no longer believed to align with positive health outcomes) but, generally, removal of a measure for other reasons would also occur through rulemaking.

Commenters to last year's Notice of Proposed Rulemaking (NPRM) expressed overall support for the use of the hierarchical clustering algorithm which is the methodology used for determining the non-Consumer Assessment of Healthcare Providers and Systems (CAHPS) measure-specific cut points. The cut points are used to separate a measure-specific distribution of scores into distinct, non-overlapping groups, or star categories. However, the majority of commenters also recommended some enhancements be made to the proposed clustering methodology to capture the attributes that they consider important. Commenters expressed a strong preference for cut points that are stable, predictable, and free from undue influence of outliers. Further, some commenters expressed a preference for caps to limit the amount of movement in cut points from year to year. CMS did not finalize any changes in last year's rule to the clustering algorithm for the determination of the non-CAHPS cut points for the conversion of measure scores to measure-level Star Ratings to allow the necessary time to simulate and examine the feasibility and impact of the suggestions provided in response to the proposed rule. In addition, CMS evaluated the degree to which the simulations captured the desired attributes identified by the commenters.

At this time, we are proposing enhancements to the cut point methodology for non-CAHPS measures. We are also proposing substantive updates to the specifications for 2 measures for the 2022 Star Ratings and substantive updates to the specifications for 1 measure for the 2023 Star Ratings. We are also proposing rules for calculating Star Ratings in the case of extreme and uncontrollable circumstances. Unless otherwise stated, data would be collected and performance would be measured as described in these proposed rules and regulations for the 2020 measurement period; the associated quality Star Ratings would be released prior to the annual election period held in late 2021 for the 2022 contract year and would be used to assign Quality Bonus Payment ratings for the 2023 payment year. Because of the timing of the release and use in conjunction with the annual coordinated election period, these would be the ''2022 Star Ratings.''

b. Definitions

We propose to add the following definitions for the respective subparts in part 422 and part 423, in paragraph (a) of §§ 422.162 and 423.182, respectively. These proposed new definitions are relevant for our proposed policies and are used in that context.

- *Absolute percentage cap* is a cap applied to non-CAHPS measures that are on a 0 to 100 scale that restricts movement of the current year's measure-threshold-specific cut point to no more than the stated percentage as compared to the prior year's cut point.
- *Cut point cap* is a restriction on the change in the amount of movement a measure-threshold-specific cut point can make as compared to the prior year's measure-threshold-specific cut point. A cut point cap can restrict upward movement, downward movement, or both.
- *Guardrail* is a bidirectional cap that restricts both upward and downward movement of a measure-threshold-specific cut point for the current year's measure-level Star Ratings as compared to the prior year's measure-threshold-specific cut point.
- *Mean resampling* refers to a technique where measure-specific scores for the current year's Star Ratings are randomly separated into 10 equal-sized groups. The hierarchical clustering algorithm is done 10 times, each time leaving one of the 10 groups out. The method results in 10 sets of measure-specific cut points. The mean cut point for each threshold per measure is calculated using the 10 values.

By leaving out one of the 10 groups for each run, 9 of the 10 groups which is 90 percent of the applicable measure scores are used for each run of the clustering algorithm.

- *Restricted range* is the difference between the maximum and minimum measure score values using the prior year measure scores excluding outer fence outliers (first quartile − 3 * Interquartile Range (IQR) and third quartile + 3 * IQR).[19]

We propose to specify in the definition the criteria used to identify the values that correspond to the outer fences which are used to identify extreme outliers in the data. Outer fence outliers use established statistical criteria for the determination of the boundary values that correspond to the outer fences. The outer fences are the boundary values for an outer fence outlier such that any measure score that either exceeds the value of the upper outer fence (third quartile + 3*IQR) or that is less than the lower outer fence (first quartile − 3 * IQR) is classified as an outer fence outlier and excluded from the determination of the value of the restricted range cap.

- *Restricted range cap* is a cap applied to non-CAHPS measures that restricts movement of the current year's measure-threshold-specific cut point to no more than the stated percentage of the restricted range of a measure calculated using the prior year's measure score distribution.

We welcome comments on these definitions.

c. Measure-Level Star Ratings (§§ 422.166(a), 423.186(a))

At §§ 422.166(a) and 423.186(a) we codified the methodology for calculating Star Ratings at the measure level. The methodology for non-CAHPS measures employs a hierarchical clustering algorithm to identify the gaps that exist within the distribution of the measure-specific scores to create groups (clusters) that are then used to identify the cut points. The Star Ratings categories are designed such that the scores in the same Star Ratings category are as similar as possible and the scores in different Star Ratings categories are as different as possible. The current methodology uses only data that

[19] The first quartile is median of the lower half of the data, or in other words the value in the data once arranged in numerical order that divides the lower half into two equal parts. The third quartile is the median of the upper half of the data.

correspond to the measurement period of the data used for the current Star Ratings program. The cut points, as implemented now, are responsive to changes in performances from one year to the next. Changes in the measure-level specific cut points across a Star Ratings year reflect lower or higher measure performance than the prior year, as well as shifts in the distribution of the scores.

In the April 2018 final rule, CMS detailed the goals of the Star Ratings program. The overarching goals of the Star Ratings program and the specific sub-goals of setting cut points serve as the rationale for any proposed changes.

The Star Ratings display quality information on Medicare Plan Finder to help beneficiaries, families, and caregivers make informed choices by being able to consider a plan's quality, cost, and coverage; to provide information for public accountability; to incentivize quality improvement; to provide information to oversee and monitor quality; and to accurately measure and calculate scores and stars to reflect true performance. In addition, pursuant to section 1853(o) of the Act and the Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes Final Rule (76 FR 21485 through 21489), the Star Ratings are also used to assign Quality Bonus Payments as provided in § 422.558(d).

To separate a distribution of measure scores into distinct groups or star categories, a set of values must be identified to separate one group from another group. The set of values that break the distribution of the scores into non-overlapping groups is referred to as a set of cut points. The primary goal of any cut point methodology is to disaggregate the distribution of scores into discrete categories such that each grouping accurately reflects true performance.

The current MA Star Ratings methodology converts measure-specific scores to measure-level Star Ratings so as to categorize the most similar scores within the same measure-level Star Rating while maximizing the differences across measure-level Star Ratings. To best serve their purpose, the Star Ratings categories must capture meaningful differences in quality across the Star Ratings scale and minimize the risk of misclassification. For example, it would be considered a misclassification if a ''true'' 4-star contract were scored as a 3-star contract, or vice versa, or if nearly-identical contracts in different measure-level star categories were mistakenly identified. CMS currently employs hierarchical clustering to identify the cut points for non-CAHPS measures to ensure that the measure-level Star Ratings accurately reflect true performance and provide a signal of quality and performance on Medicare Plan Finder to empower beneficiaries, families, and caregivers to make informed choices about plans that would best align with their priorities.

We solicited comments regarding the approach to convert non-CAHPS measure scores to measure-level Star Ratings (82 FR 56397 through 56399). We requested stakeholders to provide input on the desirable attributes of cut points and recommendations to achieve the suggested characteristics. In addition, we requested that commenters either suggest alternative cut point methodologies or provide feedback on several options detailed in the regulation such as setting the cut points by using a moving average, using the mean of the 2 or 3 most recent years of data, or restricting the size of the change in the cut points from 1 year to the next.

The commenters identified several desirable attributes for the cut points that included stability, predictability, attenuation of the influence of outliers, restricted movement of the cut points from 1 year to the next, and either pre-announced cut points before the plan preview period or pre-determined cut points before the start of the measurement period. In the April 2018 final rule (83 FR 16567), we expressed appreciation for our stakeholders' feedback and stated our intent to use it to guide the development of an enhanced methodology. So as not to implement a methodology that may inordinately increase the risk of misclassification, CMS has analyzed and simulated alternative options to assess the impact of any enhancements on the Star Ratings program and assess the degree to which the alternative methodology captures the desirable attributes that were identified by stakeholders. While CMS balances the request of stakeholders to increase predictability and stability of the cut points from year to year, the goals of the Star Ratings program, the integrity of the methodology, and the intent of the cut point methodology remain the same. The intent of the cut point methodology is still to accurately measure true performance. We intend our proposal to serve these goals and solicit comment on whether we have met our objective in this respect.

A Technical Expert Panel (TEP), comprised of representatives across various stakeholder groups, convened on May 31, 2018 to provide feedback to CMS's Star Ratings contractor (currently RAND Corporation) on the Star Ratings framework, topic areas, methodology, and operational measures. Information about the current members of the TEP can be found at *https://www.rand.org/content/dam/rand/pubs/conf_proceedings/CF300/CF391/RAND_CF391.members.pdf.* One topic discussed was possible enhancements to the clustering methodology used to convert non-CAHPS measure scores to measure-level Star Ratings. The TEP provided input on the importance of the cut point attributes of predictability and stability. To increase the level of predictability, several TEP members discussed the use of caps. Further, the TEP suggested that the influence of outliers should be addressed in the methodology. While some TEP members spoke to the utility of pre-announced thresholds to allow contracts to make decisions, other TEP members stated that there are real risks in doing so. After reviewing the data that would need to be employed for pre-announced cut points along with the measure score and cut point trends, TEP members were concerned about using older data to predict cut points. For example, high performers may stop their focus on particular measures if they knew in advance that they would receive a 5-star rating. Likewise, contracts whose measure performance would not reach high Star Ratings may stop working on achieving a goal perceived to be unattainable. Some of the TEP members requested that CMS, in addition to addressing outliers, establish guardrails so cut points do not fluctuate too much from year to year. Additional information about the TEP can be found at *http://www.rand.org/star-ratings-analyses.*

CMS has examined numerous alternative methodologies to minimize the influence of outliers, to restrict the upward or downward movement of cut points from one year to the next, and to simulate prediction models to allow either limited advance notice or full advance notice of cut points prior to the measurement period. As part of our analyses, we have analyzed trends in performance across the Star Ratings measures. The ability to announce cut points before (full advance notice) or during (partial advance notice) the measurement period requires the use of modeling and older data to project the cut points, as well as the need for an alternative methodology for new measures introduced to the Star Ratings program. Modeling is challenging given differences in the performance trends over time across the Star Ratings measures, thus a single approach for

predicting all future performance does not accurately reflect performance for all measures.

Using prediction models to establish future cut points may have unintended consequences and misalign with the underlying goals of the Star Ratings program and sub-goals of setting cut points. Predicting future cut points using older data can lead to both over or under-estimations of performance which results in a distorted signal of the Star Ratings. Over projections in the cut points will result in higher cut points and lower measure-level Star Ratings. Conversely, under projections can lead to lower cut points and higher measure-level Star Ratings. The risk of misclassification is heightened when the accuracy of the projected cut points is diminished. The use of older data for setting cut points does not allow the Star Ratings to be responsive to changes in performance in the current year. Furthermore, setting cut points in advance of the measurement year may lead to MA organizations and Part D sponsors not focusing on certain areas once they achieve a set threshold, eliminating incentives for improvement.

For example, CMS provided incentives for eligible providers to adopt certified Electronic Health Records (EHRs) and report quality measures under the Meaningful Use (MU) initiative. There were large gains in performance for a subset of Star Ratings measures that were enabled through the EHR, a structural change among health care providers in the delivery of care. Further, an examination of performance over time of EHR-enabled measures indicates a decrease in variability of measure scores with contract performance converging toward greater uniformity. Modeling future performance using past performance would fail to capture the large gains in performance in the EHR-enabled measures, which would have resulted in cut points that were artificially low and measure-level Star Ratings that were higher than true performance.

Pre-announced cut points for other subsets of measures in the Star Ratings would present different challenges as compared to EHR-enabled measures. Performance on new measures typically has more room to improve, and large year-to-year gains are possible and desirable from a quality improvement perspective. Projecting cut points using older data from periods of rapid improvement would artificially inflate future cut points which would cause artificially low measure-level Star Ratings. Measures that demonstrate very slow, consistent growth over time could have projected cut points that are artificially high. The further the projection is in advance of the measurement period, the larger the potential for unintended consequences. In addition, there exists the possibility of external factors, other than structural, that are unanticipated and unforeseen that could impact the distribution of scores for which modeling would not capture.

Some of the challenges of full or partial advance notice include all of the following:

- Older data often do not accurately reflect current performance.
- The trend in average performance is not always linear.
- External or structural factors may occur that can lead to substantial changes from period to period rather than steady slow year-over-year improvement.
- Larger gains in performance year to year exist for relatively new measures, compared to more established measures.
- The rate of change is less likely to be linear at lower threshold levels where contracts have greater opportunities for improvement.
- Decreasing variation in measure scores reflects greater improvements in performance for lower versus higher-performing contracts—contract performance is converging over time toward greater uniformity.

These challenges are critical to consider because if we modify the current methodology to predict (or set) cut points using older data and a single model across all measures, we risk causing unintended consequences such as significantly diminishing incentives for improvement or having the Star Ratings misaligned with changes in performance that may be due to external or structural factors.

Based on stakeholder feedback and analyses of the data, we propose two enhancements to the current hierarchical clustering methodology that is used to set cut points for non-CAHPS measure stars in §§ 422.166(a)(2)(i) and 423.186(a)(2)(i). The first proposed enhancement is mean resampling. With mean resampling, measure-specific scores for the current year's Star Ratings are randomly separated into 10 equal-sized groups. The hierarchical clustering algorithm is done 10 times, each time leaving one of the 10 groups out. The method results in 10 sets of measure-specific cut points. The mean cut point for each threshold per measure is calculated using the 10 values. Mean resampling reduces the sensitivity of the clustering algorithm to outliers and reduces the random variation that contributes to fluctuations in cut points and, therefore, improves the stability of the cut points over time. Mean resampling uses the most recent year's data for the determination of the cut points; thus, it does not require assumptions for predicting cut points over time and it continues to provide incentives for improvement in measure scores. The drawback of mean resampling alone is that it does not restrict the movement of the cut points, so the attribute of predictability is not fully captured with this methodology.

To increase the predictability of the cut points, we also propose a second enhancement to the clustering algorithm: A guardrail for measures that have been in the Part C and D Star Ratings program for more than 3 years. The proposed guardrail of 5 percent would be a bi-directional cap that restricts movement both above and below the prior year's cut points. A 5 percent cap restricts the movement of a cut point by imposing a rule for the maximum allowable movement per measure threshold; thus, it allows a degree of predictability. The trade-off for the predictability provided by bi-directional caps is the inability to fully keep pace with changes in performance across the industry. While cut points that change less than the cap would be unbiased and keep pace with changes in the measure score trends, changes in overall performance that are greater than the cap would not be reflected in the new cut points. A cap on upward movement may inflate the measure-level Star Ratings if true gains in performance improvements cannot be fully incorporated in the current year's ratings. Conversely, a cap on downward movement may decrease the measure-level Star Ratings since the ratings would not be adjusted fully for downward shifts in performance.

A measure-threshold-specific cap can be set multiple ways and the methodology may differ based on whether the measure is scored on a 0 to 100 scale or an alternative scale. For measures on a 0 to 100 scale, the cap can restrict the movement of the measure cut points from one year to the next by a fixed percentage, such as an absolute 5 percentage point cap. For measures not on a 0 to 100 scale, the cap can be determined for each measure by using a percentage of the measure's score distribution or a subset of the distribution, such as 5 percent of the range of the prior year scores without outer fence outliers, referred to as a restricted range cap. Alternatively, a restricted range cap can be used for all measures, regardless of scale, using a cap based on the range of the prior year scores without outliers. We propose an absolute 5 percentage point cap for all

measures scored on a 0 to 100 scale and 5 percent of the restricted range for all measures not on a 0 to 100 scale, but we are also considering alternatives to the 5 percent cap, such as using 3 percent; we believe that any cap larger than 5 percent would not provide the predictability requested by stakeholders that we are trying to incorporate. While smaller caps provide more predictability, it is more likely that the cut points will not keep pace with changes in measure scores in the industry as the cap size gets smaller, and may require future larger one-time adjustments to reset the measure cut points. Therefore, we are not sure that a smaller cap, even at a 3 percent threshold, would meet our programmatic needs and goals of providing accurate pictures of the underlying performance of each contract and its comparison to other contracts. We are proposing 5 percent because the use of the cap allows predictability of the cut points from year to year, but also balances the desire to continue to create incentives for contracts to focus on the quality of care of their enrollees and strive to improve performance. If the cut points are not keeping pace with the changes in the scores over time, CMS may need to propose in the future how to periodically adjust the cut points to account for significant changes in industry performance.

In summary, we propose to modify §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) to add mean resampling to the current clustering algorithm to attenuate the effect of outliers, and measure-specific caps in both directions to provide guardrails so that the measure-threshold-specific cut points do not increase or decrease more than the cap from one year to the next. We propose a 5 percentage point absolute cap for measures on a 0 to 100 scale and a 5 percent restricted range cap ((0.05) * (maximum value − minimum value), where the maximum and minimum values are calculated using the prior year's measure score distributions excluding outer fence outliers). For any new measures that have been in the Part C and D Star Rating program for 3 years or less, we propose to use the hierarchal clustering methodology with mean resampling for the first 3 years in the program in order to not cap the initial increases in performance that are seen for new measures. We welcome comments on this proposal, including comments on the percentage used for the cap, whether the cap should be an absolute percentage difference for measures on a 0 to 100 scale, whether the cap should be a percent of the range of prior year scores without outliers for all measures or for the subset of measures not on a 0 to 100 scale, whether the cap should be in both the upward and downward directions, and alternative methods to account for outliers.

d. Updating Measures (§§ 422.164, 423.184)

In the April 2018 final rule (83 FR 16537), CMS stated that due to the regular updates and revisions made to measures, CMS would not codify a list of measures and specifications in regulation text; CMS adopted a final list of measures for the contract year 2019 measurement period and indicated how changes to that list—additions, updates, removals—would be done in the future, using the Advance Notice and Rate Announcement under section 1853(b) of the Act or rulemaking. The regulations at §§ 422.164 and 423.184 specify the criteria and procedure for adding, updating, and removing measures for the Star Ratings program. CMS lists the measures used for the Star Ratings each year in the Technical Notes or similar guidance document with publication of the Star Ratings. In this rule, CMS is proposing measure changes to the Star Ratings program for performance periods beginning on or after January 1, 2020 and performance periods beginning on or after January 1, 2021. For new measures and substantive updates to existing measures, as described at §§ 422.164(c) and (d)(2), and §§ 423.184(c) and (d)(2), CMS will initially announce and solicit comment through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act and subsequently propose these measures through rulemaking to be added to the Star Ratings program. Proposals here for substantive updates have been discussed in prior Call Letters (contract years 2018 and 2019). We will continue the process of announcing our intent with regard to measure updates in future Call Letters. Any measures with substantive updates must be on the display page for at least 2 years before use in the Star Ratings program. For new measures and measures with substantive updates, as described at §§ 422.166(e)(2) and 423.186(e)(2), the measure will receive a weight of 1 for the first year in the Star Ratings program. In the subsequent years, the measure will be assigned the weight associated with its category.

(1) Proposed Measure Updates

(a) Controlling High Blood Pressure (Part C)

Due to the release of new hypertension treatment guidelines from the American College of Cardiology and American Heart Association,[20] NCQA has implemented updates to the Controlling High Blood Pressure measure for HEDIS 2019. NCQA has revised the blood pressure target to <140/90 mmHg. NCQA has also made some structural changes to the measure that included allowing two outpatient encounters to identify the denominator and removing the medical record confirmation for hypertension, allowing the use of telehealth services for one of the outpatient encounters in the denominator, adding an administrative approach that utilizes CPT category II codes for the numerator, and allowing remote monitoring device readings for the numerator. Given the change to the blood pressure target and our rules for moving measures with substantive changes to the display page, this measure will be moved to the display page for the 2020 and 2021 Star Ratings. We propose to return this measure as a measure with substantive updates by the measure steward (NCQA) to the 2022 Star Ratings using data from the 2020 measurement year with, as required by § 422.164(d)(2) and § 422.166(e)(2), a weight of 1 for the first year and a weight of 3 thereafter.

(b) MPF Price Accuracy (Part D)

Continued evaluation of sponsors' pricing data used by beneficiaries is important; therefore, we propose to make enhancements to the MPF Price Accuracy measure to better measure the reliability of a contract's MPF advertised prices. In accordance with § 423.184(d)(2), the substantively updated measure would be a display measure for 2020 and 2021 and we are proposing to use it in the 2022 Star Ratings in place of the existing MPF Price Accuracy measure, which will remain in the Star Ratings until that replacement under § 423.184(d)(2). The proposed update would measure the magnitude of difference, as well as the frequency of price differences. We propose to implement the following changes for this measure:

[20] See Whelton P.K., Carey R.M., Aronow W.S., et al. (2018). Guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Journal of the American College of Cardiology. 71(19): e127–e248. Available at *http://www.onlinejacc.org/content/71/19/e127?_ga=2.143510773.1362500146.1536262802-126396490.1536262802.*

• Factor both how much and how often prescription drug event (PDE) prices exceeded the prices reflected on the MPF by calculating a contract's measure score as the mean of the contract's Price Accuracy and Claim Percentage scores, based on the indexes in this rule:

++ The Price Accuracy index compares point-of-sale PDE prices to plan-reported MPF prices and determines the magnitude of differences found. Using each PDE's date of service, the price displayed on MPF is compared to the PDE price. The Price Accuracy index is computed as:

(Total amount that PDE is higher than MPF + Total PDE cost)/(Total PDE cost)

++ The Claim Percentage index measures the percentage of all PDEs that meet the inclusion criteria with a total PDE cost higher than total MPF cost to determine the frequency of differences found. The Claim Percentage index is computed as:

(Total number of claims where PDE is higher than MPF)/(Total number of claims)

++ The best possible Price Accuracy index is 1 and the best possible Claim Percentage index is 0. This indicates that a plan did not have PDE prices greater than MPF prices.

++ A contract's measure score is computed as:

—Price Accuracy Score = 100 − ((Price Accuracy Index − 1) * 100)

—Claim Percentage Score = (1 − Claim Percentage Index) * 100

—Measure Score = (0.5 * Price Accuracy Score) + (0.5 * Claim Percentage Score)

• Increase the claims included in the measure:

++ Expand the days' supply of claims included from 30 days to include claims with fills of 28–34, 60–62, or 90–100 days.

++ Identify additional retail claims using the PDE-reported Pharmacy Service Type code. Claims for pharmacies that are listed as retail in the MPF Pharmacy Cost file and also have a pharmacy service type on the PDE of either Community/Retail or Managed Care Organization (MCO) will be included.

• Round a drug's MPF cost to 2 decimal places for comparison to its PDE cost. Post-rounding, the PDE cost must exceed the MPF cost by at least one cent ($0.01) in order to be counted towards the accuracy score (previously, a PDE cost which exceeded the MPF cost by $0.005 was counted). A contract may submit an MPF unit cost up to 5 digits, but PDE cost is always specified to 2 decimal places.

Under our proposed update, PDEs priced lower than the MPF display pricing will continue to be ignored and will not have an impact on the measure score or rating. Only price increases are counted in the numerator for this measure. We propose to add this updated measure to the 2022 Star Ratings based on the 2020 measurement year with a weight of 1.

(3) Plan All-Cause Readmissions (Part C)

NCQA is modifying the Plan All-Cause Readmissions measure for HEDIS 2020 (measurement year 2019). The measure assesses the percentage of hospital discharges resulting in unplanned readmissions within 30 days of discharge. The changes made by NCQA are: Adding observation stays as hospital discharges and readmissions in the denominator and the numerator; and removing individuals with high frequency hospitalizations. These changes were implemented by the measure steward (NCQA) based on the rise in observation stays to ensure the measure better reflects patient discharge and readmission volumes. Removing individuals with high frequency hospitalizations from the measure calculation allows the readmissions rates not to be skewed by this population. To date, CMS has only included the 65+ age group in the Plan All-Cause Readmissions measure. CMS is proposing to combine the 18–64 and 65+ age groups as the updated measure specifications are adopted and to use NCQA's new recommendation of 150 as the minimum denominator. Given the substantive nature of the proposed updates for this measure, it would be moved to display for the 2021 and 2022 Star Ratings under our proposal and § 422.164(d)(2). We propose to return this measure as a measure with substantive updates by the measure steward (NCQA) to the 2023 Star Ratings using data from the 2021 measurement year with, as required by § 422.164(d)(2) and § 422.166(e)(2), a weight of 1 for the first year and a weight of 3 thereafter.

(4) Improvement Measures (Parts C and D)

The process for identifying eligible measures to be included in the improvement measure scores is specified as a series of steps at §§ 422.164(f)(1) and 423.184(f)(1). As part of the first step, the measures eligible to be included in the Part C and D improvement measures are identified. Only measures that have a numeric score for each of the 2 years examined are included. We propose to add an additional rule at §§ 422.164(f)(1)(iv) and 423.184(f)(1)(iv) that would exclude any measure that receives a measure-level Star Rating reduction for data integrity concerns for either the current or prior year from the improvement measure(s). The proposed new standard would ensure that the numeric scores for each of the 2 years are unbiased. If a measure's measure-level Star Rating receives a reduction for data integrity concerns in either of the 2 years, the measure would not be eligible to be included in the improvement measure(s) for that contract.

Table 1: Proposed Additions and Updates to Individual Star Rating Measures

The measure descriptions listed in the tables are high-level summaries. The Star Ratings measure specifications supporting document, *Medicare Part C & D Star Ratings Technical Notes,* provides detailed specifications for each measure. Detailed specifications include, where appropriate, the identification of a measure's: (1) Numerator, (2) denominator, (3) calculation, (4) time frame, (5) case-mix adjustment, and (6) exclusions. The Technical Notes document is updated annually. In addition, where appropriate, the Data Source descriptions listed in this table reference the technical manuals of the measure stewards. The annual Star Ratings are produced in the fall of the prior year to assist beneficiaries in choosing their health and drug plan during the annual open enrollment. For example, Star Ratings for the year 2022 are produced in the fall of 2021.

1. If a measurement period is listed as 'the calendar year 2 years prior to the Star Ratings year' and the Star Ratings year is 2022, the measurement period is referencing the January 1, 2020 to December 31, 2020 period.

2. For CAHPS, HOS, and HEDIS/HOS measures, the measurement period is listed as 'most recent data submitted for the survey of enrollees.' See measure stewards' technical manuals, as referenced in Data Source column, for the specific measurement periods of the most recent data submitted.

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TABLE 1A: PROPOSED UDATES TO INDIVIDUAL STAR RATING MEASURES FOR PERFORMANCE PERIODS BEGINNING ON OR AFTER JANUARY 1, 2020

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	NQF Endorsement	Statistical Method for Assigning Star Ratings	Reporting Requirements (Contract Type)
Part C Measure								
Controlling Blood Pressure (CBP)	Percent of plan members 18-85 years of age who had a diagnosis of hypertension (HTN) and whose blood pressure was adequately controlled (<140/90).	Managing Chronic (Long Term) Conditions	Intermediate Outcome Measure Weight of 3	HEDIS*	The calendar year 2 years prior to the Star Ratings year	#0018	Clustering	MA-PD and MA-only
Part D Measure								
MPF Price Accuracy	A score comparing the prices members actually pay for their drugs to the drug prices the plan provided for the Medicare Plan Finder website.	Drug Safety and Accuracy of Drug Pricing	Process Measure Weight of 1	PDE data, MPF Pricing Files	The calendar year 2 years prior to the Star Ratings year	Not Applicable	Clustering	MA-PD and PDP

* NCQA HEDIS Technical Specifications, Volume 2

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TABLE 1B: PROPOSED UPDATES TO INDIVIDUAL STAR RATING MEASURES FOR PERFORMANCE PERIODS BEGINNING ON OR AFTER JANUARY 1, 2021

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	NQF Endorsement	Statistical Method for Assigning Star Ratings	Reporting Requirements (Contract Type)
Part C Measure								
Plan All-Cause Readmissions (PCR)	Percent of acute inpatient stays that were followed by an unplanned acute readmission or an observation stay for any diagnosis within 30 days, for members ages 18 and over. Rates are risk-adjusted.	Managing Chronic (Long Term) Conditions	Intermediate Outcome Measure Weight of 3	HEDIS*	The calendar year 2 years prior to the Star Ratings year	#1768	Clustering	MA-PD and MA-only, except for 1876 Cost Plans

* NCQA HEDIS Technical Specifications, Volume 2

(5) Data Integrity

At §§ 422.164(g)(1)(iii) and 423.184(g)(1)(ii), CMS codified a policy to make scaled reductions to the Star Ratings for a contract's Part C or Part D appeals measures because the relevant Independent Review Entity (IRE) data are not complete based on the Timeliness Monitoring Project (TMP) or audit information. The reduction is applied to the measure-level Star Ratings for the applicable appeals measures. We propose adding an additional regulatory provision at §§ 422.164(g)(1)(iii)(O) and 423.184(g)(1)(ii)(M) that would assign a 1-star rating to the applicable appeals measure(s) if a contract fails to submit TMP data for CMS's review to ensure the completeness of their IRE data. We believe it is appropriate to assume that there is an issue related to the performance when the MA organization or Part D plan sponsor has refused to provide information for the purposes of our oversight of the compliance with the appeals requirements. Our proposal to modify measure-specific ratings due to data integrity issues is separate from any CMS compliance or enforcement actions related to a sponsor's deficiencies; these rating reductions are necessary to avoid falsely assigning a high star to a contract, especially when the MA organization or Part D sponsor has refused to submit data for us to evaluate performance in this area and to ensure that the data submitted to the IRE are complete.

(6) Review of Sponsors' Data

At §§ 422.164(h)(1) and 423.184(h)(1), CMS proposes to codify a policy regarding the deadlines for an MA organization or Part D plan sponsor to request CMS or the IRE to review a contract's appeals or CMS to review a contract's Complaints Tracking Module (CTM) data. For example, information regarding the Part C and Part D appeals process is available to MA organizations and is updated daily on the IRE website. Additionally, sponsors can access the Part D Appeals Reports under the Performance Metrics pages in HPMS. To allow enough time for the IRE to make any necessary changes to ensure the accuracy of a contract's measure score, we are proposing that requests for CMS or the IRE to review contract data must be received no later than June 30 of the following year in order to have time to use accurate information in the Star Ratings calculations (for example, changes to contract year 2018 appeals data must be made by June 30, 2019 for the 2020 Star Ratings). Reopenings are not taken into account under this proposed deadline for corrections to the IRE data. When the decision is evaluated for purposes of the appeals measures, if a reopening occurs and is decided prior to May 1, the revised determination is used in place of the original reconsidered determination. If the revised determination occurs on or after May 1, the original reconsidered determination is used.

Similarly, we propose that any requests for adjustments following CMS's CTM Standard Operating Procedures for the complaints measures be made by June 30 of the following year in order for the changes to be reflected in a contract's Star Ratings data (for example, changes to contract year 2018 complaints data must be made by June 30, 2019 for the 2020 Star Ratings).

e. Extreme and Uncontrollable Circumstances

Extreme and uncontrollable circumstances such as natural disasters can directly affect Medicare beneficiaries and providers, as well as the Parts C and D organizations that provide them with important medical care and prescription drug coverage. These circumstances may negatively affect the underlying operational and clinical systems that CMS relies on for accurate performance measurement in the Star Ratings program, all without fault on the part of the MA organization or Part D plan sponsor. We propose to adjust the Star Ratings to take into account the effects of extreme and uncontrollable circumstances that occurred during the performance or measurement period. CMS is also concerned that certain natural disasters and emergencies may interfere in plans' abilities to provide services for their enrollees. In this rule, we describe proposed policies for identifying affected contracts and adjusting the Star Ratings measures. These policies are largely the same as those described in the 2019 final Call Letter, with the substantive exception of eliminating the difference-in-differences adjustment for survey data. The difference-in-differences adjustment showed no consistent, negative impact of extreme and uncontrollable circumstances on the 2019 Star Ratings; therefore, we are eliminating this adjustment to simplify the methodology for calculating Star Ratings in cases of extreme and uncontrollable circumstances. We propose to codify a series of special rules for calculation of the Star Ratings of certain contracts in certain extreme and uncontrollable circumstances in paragraph (i) of §§ 422.166 and 423.186.

We propose that the adjustments be tailored to the specific areas experiencing the extreme and uncontrollable circumstance in order to avoid over-adjustment or adjustments that are unnecessary. Health and drug plans can serve enrollees across large geographic areas, and thus they may not be impacted in the same manner as healthcare providers such as hospitals or medical centers in specific physical locations. To ensure that the Star Ratings adjustments focus on the specific geographic areas that experienced the greatest adverse effects from the extreme and uncontrollable circumstance and are not applied to areas sustaining little or no adverse effects, our proposal is to target the adjustments to specific contracts and to further specify and limit the adjustments.

(1) Identification of Affected Contracts

In paragraph (i)(1) of §§ 422.166 and 423.186, we propose to identify MA and Part D contracts affected by extreme and uncontrollable circumstances during the performance or measurement period that may have affected their performance on Star Ratings measures or their ability to collect the necessary measure-level data. These ''affected contracts'' would be the contracts eligible for the adjustments specified in this proposed rule to take into account the effects of the extreme and uncontrollable circumstances. For an MA or Part D contract to be considered an affected contract under our proposal, the contract would need to meet all of the following criteria:

- The contract's service area is within an ''emergency area'' during an ''emergency period'' as defined in Section 1135(g) of the Act.
- The contract's service area is within a county, parish, U.S. territory or tribal area designated in a major disaster declaration under the Stafford Act and the Secretary exercised authority under section 1135 of the Act based on the same triggering event(s).
- A certain minimum percentage (25 percent for measure star adjustments or 60 percent for exclusion from cut point and Reward Factor calculations) of the enrollees under the contract must reside in a Federal Emergency Management Agency (FEMA)-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance.

We propose to identify an area as having experienced extreme and uncontrollable circumstances if it is within an ''emergency area'' and ''emergency period'' as defined in section 1135(g) of the Act, and also is

within a county, parish, U.S. territory or tribal government designated in a major disaster declaration under the Stafford Act, and the Secretary exercised authority under section 1135 of the Act based on the same triggering event(s) (*https://www.phe.gov/emergency/news/healthactions/section1135/Pages/default.aspx*). Major disaster areas are identified and can be located on FEMA's website at *https://www.fema.gov/disasters.* To ensure the policy is applied to those contracts most likely to have experienced the greatest adverse effects, we propose to narrow it to apply to contracts with a certain minimum percentage of enrollees residing in an area declared as an Individual Assistance area because of the disaster declaration. Individual Assistance includes assistance to individuals and households, crisis counseling, disaster case management, disaster unemployment assistance, disaster legal services, and the disaster Supplemental Nutrition Assistance Program. We focus on enrollees residing in counties eligible for Individual Assistance because of a major disaster, because most Star Ratings measures are based on services provided directly to beneficiaries in their local area. Health and drug plans can serve enrollees across large geographic areas, and thus they may not be impacted in the same manner as healthcare providers such as hospitals or medical centers in specific physical locations. Therefore, we believe adjustments to the Star Ratings are most appropriately targeted to contracts serving beneficiaries who were eligible for individual and household assistance because of the disaster declaration.

For adjustments, at least 25 percent or 60 percent of the enrollees under the contract must reside in Individual Assistance areas identified because of the extreme and uncontrollable circumstances. This ensures that the adjustments are limited to contracts that we believe may have experienced a real impact from the extreme and uncontrollable circumstance in terms of operations or ability to serve enrollees. In calculations for the 2019 Star Ratings, we observed that contracts tend to have either very few enrollees impacted or most of their enrollees impacted due to the nature of contracts either covering a broad region or a localized area. If 1 out of 4 enrollees was impacted during the period of the year when the disaster hit, we believe there is a small chance that scores may have been impacted. The selection of the exclusion of numeric measures scores from contracts with 60 percent or more enrollees impacted from the determination of the cut points is conservative in case scores are impacted in contracts where a clear majority or all of the enrollees are impacted. Using the Individual Assistance major disaster declaration as a requirement for the extreme and uncontrollable event policy also ensures that the policy applies only when the event is extreme, meriting the use of special adjustments to the Star Ratings.

We propose that contracts that do not meet the definition of an ''affected contract'' would not be eligible for any adjustments based on the occurrence of the extreme and uncontrollable circumstances. However, meeting the criteria to be an affected contract is not sufficient for all the adjustments we propose.

(2) CAHPS Adjustments

For CAHPS, we propose two different types of special rules for affected contracts: exemption from having to administer the CAHPS survey or adjustments to the Star Ratings on the CAHPS measures if the affected contract must administer the CAHPS survey. CAHPS measures are based on a survey conducted early in the year in which the Star Ratings are released that is, the year before the year to which the Star Ratings are applicable. For example, the CAHPS survey in early 2019 will be used for the 2020 Star Ratings, which are released in late 2019, before the annual coordinated election period for 2020.

We propose at §§ 422.166(i)(2)(i) and 423.186(i)(2)(i), that an MA and Prescription Drug Plan contract, even if it is an affected contract, must administer the CAHPS survey unless the contract demonstrates to CMS that the required sample for the CAHPS survey cannot be contacted because a substantial number of the contract's enrollees are displaced due to a FEMA-designated disaster in the prior calendar year and requests and receives a CMS approved exception. We believe that displacement of a substantial number of the contract's enrollees would make it practically impossible to contact the required sample for the CAHPS survey. For an affected contract that receives the exemption from administering the CAHPS survey, we propose at 422.166(i)(2)(iii) and 423.186(i)(2)(iii) that the affected contract would receive the prior year's CAHPS measure stars (and corresponding measure scores).

For other affected contracts, we propose an adjustment to the CAHPS scores and Star Ratings based on the administered survey and the percentage of enrollees in the affected contract that reside in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance. We propose that affected contracts with at least 25 percent of enrollees residing in Individual Assistance areas at the time of the extreme and uncontrollable circumstance would receive the higher of the previous year's Star Rating or the current year's Star Rating (and corresponding measure score) for each CAHPS measure (including the annual flu vaccine measure). For example, for the 2022 Star Ratings for affected contracts, we would take the higher of the 2021 Star Ratings or the 2022 Star Ratings for each CAHPS measure. The affected contract would receive the CAHPS measure score for the corresponding Star Rating year chosen. We propose the 25 percent threshold to avoid including contracts with very few enrollees impacted. The measure-level scores for contracts with very few enrollees impacted should not be adversely affected by these extreme and uncontrollable circumstances. If a small percentage of enrollees were impacted by an extreme and uncontrollable circumstance, it should not have a significant impact on measure scores.

(3) HOS Adjustments

For the HOS survey, we propose to follow similar procedures as CAHPS but due to the follow-up component of HOS, the adjustment would be to the Star Ratings for the year after the completion of the follow-up HOS survey that is administered 2 years after the baseline HOS survey. For example, the 2022 Star Ratings are based on data collected from April through June 2020 and reflect experiences over the past 12 months. The data collected in 2021 will be used for the 2023 Star Ratings, so responses may reflect the impact of 2020 extreme and uncontrollable circumstances and thus, those circumstances may have an impact on the 2023 Star Ratings.

As described at proposed § 422.166(i)(3)(i), an MA contract, even if it is an affected contract, must administer the HOS surveys the year after the extreme and uncontrollable circumstance unless the contract demonstrates to CMS that the required sample cannot be contacted because a substantial number of the contract's enrollees are displaced due to a FEMA-designated disaster during the measurement period and requests and receives a CMS approved exception. For an affected contract that receives the exemption from administering the HOS survey, we propose at paragraph (i)(3)(iii) that the affected contract would receive the prior year's HOS and

HEDIS–HOS measure stars (and corresponding measure scores).

We propose at § 422.166(i)(3)(iv) that the affected contracts with at least 25 percent of enrollees residing in Individual Assistance areas at the time of the extreme and uncontrollable circumstance would receive the higher of the previous year's Star Rating or current year's Star Rating for each HOS and HEDIS–HOS measure (and corresponding measure score) for the Star Ratings 3 years after the eligible extreme and uncontrollable circumstance. As an example, for the 2023 Star Ratings for contracts affected by an extreme and uncontrollable circumstance in 2020, we would take the higher of the 2022 or 2023 Star Ratings and corresponding measure score for each HOS and HEDIS–HOS measure.

(4) HEDIS Adjustments

For HEDIS, we propose that an MA contract, even if an affected contract, would be required to report HEDIS data to CMS unless the contract demonstrates to CMS an inability to obtain both administrative and medical record data required for HEDIS measures due to a FEMA-designated disaster in the prior calendar year and requests and receives a CMS approved exception. All contracts in FEMA-designated disaster areas can work with NCQA to request modifications to the samples for measures that require medical record review. For affected contracts that have service areas with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance, we propose to take the higher of the previous year's Star Rating or current year's Star Rating (and corresponding measure score) for each HEDIS measure. For example, for the 2022 Star Ratings for affected contracts we would take the higher of the 2021 or 2022 Star Ratings for each HEDIS measure.

(5) New Measure Adjustments

At proposed §§ 422.166(i)(5) and 423.186(i)(3), we propose to implement a hold harmless provision for *new* Star Ratings measures if the inclusion of all applicable new measure(s) brings down the summary and/or overall rating. That is, for affected contracts with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance, all the new measures would be excluded from the calculation of the summary and/or overall rating if their inclusion brings a contract's summary (or in the case of MA–PD contracts, the overall) rating down.

(6) Other Star Ratings Measure Adjustments

For all other measures for affected contracts with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance (that occurs during the measurement or performance period), we propose to take the higher of the previous or current year's measure Star Rating (and then use the corresponding measure score), as described at proposed §§ 422.166(i)(6) and 423.186(i)(4). For example, for the 2022 Star Ratings for affected contracts, we would take the higher of the 2021 or 2022 Star Ratings. We propose to exclude from this adjustment policy the Part C Call Center—Foreign Language Interpreter and TTY Availability and Part D Call Center—Foreign Language Interpreter and TTY Availability measures, except for extreme and uncontrollable circumstances where there are continuing communications issues related to loss of electricity and damage to infrastructure during the call center study. These measures and the underlying performance are completely in the plan's control; we believe therefore that there should generally be no impact from the declaration of an extreme and uncontrollable circumstance on plan performance in these areas.

(7) Exclusion From Improvement Measures

Contracts must have data for at least half of the measures [21] used to calculate the Part C or Part D improvement measures to be eligible to receive a rating in each improvement measure. For affected contracts that revert back to the data underlying the previous year's Star Rating for a particular measure, we propose that measure would be excluded from both the count of measures (for the determination of whether the contract has at least half of the measures needed to calculate the relevant improvement measure) and the applicable improvement measures for the current and next year's Star Ratings as stated at proposed §§ 422.166(i)(7) and 423.186(i)(5). That is, we would follow our usual rule where to receive a Star Rating in the improvement measures, a contract must have measure scores for both years in at least half of the required measures used to calculate the Part C improvement or Part D improvement measures. The use of the data from the previous year's Star Ratings means that there is no measure score from the current year's Star Ratings, so the usual rule would eliminate the measure from consideration. As an example, for affected contracts that revert back to the 2021 Star Ratings data for a particular measure for the 2022 Star Ratings, we would exclude that measure from the count of measures and applicable improvement measures for the 2022 and 2023 Star Ratings.

(8) Missing Data

Except in cases where an exception was granted as described earlier, we propose that for all measures eligible for the extreme and uncontrollable circumstance adjustment, if an affected contract has missing data in either the current or previous year (for example, because of a biased rate or the contract is too new or too small), the final measure rating would come from the current year as described at proposed §§ 422.166(i)(8) and 423.186(i)(6). For example, if a contract affected by an eligible 2020 extreme and uncontrollable circumstance was not granted an exception for data collection and does not have sufficient data to receive a measure-level 2022 Star Rating, it would not receive a numeric rating for that measure for the 2022 Star Ratings regardless of whether it received a numeric rating in the previous year. Similarly, if an affected contract has missing measure data in the previous year but received a numeric rating in the current year, it would receive the current year's rating for its final measure rating. In both cases, the measure would be excluded from the contract's improvement score(s) following our usual rules.

(9) Cut Points for Non-CAHPS Measures

Currently, the Star Rating for each non-CAHPS measure is determined by applying a clustering algorithm to the measures' numeric value scores from all contracts required to submit the measure. The cut points are derived from this clustering algorithm. At proposed §§ 422.166(i)(9) and 423.186(i)(7), we propose to exclude from this clustering algorithm the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance. These contracts would be excluded to ensure that any impact of the extreme and uncontrollable circumstance on their measure-level

[21] See §§ 422.164(f) and 423.184(f) for more information on Part C and Part D improvement measures.

scores would not have an impact on the cut points for other contracts. However, these cut points calculated for all other non-affected contracts would be used to assess these affected contracts' measure Star Ratings. We would compare the affected contract's previous year's measure Star Ratings to the current year's measure Star Ratings to determine which is higher, and therefore used for the affected contract's Star Ratings calculations, as previously discussed. For example, for the 2022 Star Ratings we would compare the 2021 and 2022 measure Star Ratings for affected contracts.

Reward Factor. Similarly, at proposed §§ 422.166(i)(10) and 423.186(i)(8), we propose that affected contracts with 60 percent or more of their enrollees impacted would also be excluded from the determination of the performance summary and variance thresholds for the Reward Factor. However, these contracts would still be eligible for the Reward Factor based on the mean and variance calculations of other contracts.

In conclusion, we are proposing a new set of rules regarding adjusting the calculation of Star Ratings for the Parts C and D organizations who are impacted by extreme and uncontrollable circumstances to be codified at paragraphs §§ 422.166(i) and 423.186(i).

2. Improving Clarity of the Exceptions Timeframes for Part D Drugs (§§ 423.568, 423.570, and 423.572)

In this proposed rule we are proposing a change to Part D adjudication timeframes related to exception requests in cases where a prescribing physician's or other prescriber's supporting statement has not been received by the plan sponsor. We are proposing to limit the amount of time an exception request can be held open in a pending status while the Part D plan sponsor attempts to obtain the prescribing physician's or other prescriber's supporting statement. Section 1860D–4(g)(2) of the Act prescribes that in the case of a drug plan that provides for tiered cost-sharing for drugs on a formulary and provides for lower cost-sharing for preferred drugs on a formulary, a Part D enrollee may request an exception to the tiered cost-sharing. Under such an exception, a non-preferred drug could be covered under the terms applicable for preferred drugs if the prescribing physician determines that the preferred drug for treatment of the same condition either would not be as effective for the enrollee or would have adverse effects or both. Part D plan sponsors are required to have an exceptions process consistent with guidelines established by the Secretary. These guidelines are set forth at § 423.578 and permit an enrollee to request an exception to a plan's tiered cost-sharing, an exception for an off-formulary drug, and an exception to a utilization management requirement. Given the language in section 1860D–4(g)(2) of the Act referencing the determination of the prescribing physician that the preferred drug for treating the enrollee's condition would not be as effective, would have adverse effects, or both, the prescriber's supporting statement is a key component to the regulations governing the exceptions process. A plan sponsor's exceptions criteria must include a description of the criteria the plan sponsor uses to evaluate the prescribing physician's or other prescriber's statement. Due to the importance of the prescriber's supporting statement in the exceptions process, the adjudication timeframes for a coverage determination that involves an exception request do not begin until the prescribing physician's or other prescriber's supporting statement is received by the Part D plan. For example, § 423.568(b) states the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request, or, for an exception request, the physician's or other prescriber's supporting statement. Under current guidance, plans are instructed not to keep an exception request open indefinitely and are instructed to apply a reasonableness standard for holding the request open pending receipt of the prescriber's supporting statement. Chapter 18 of the Medicare Prescription Drug Manual instructs that if the plan does not receive the physician's or other prescriber's supporting statement within a reasonable period of time, the plan should make its determination based on whatever evidence exists.

We have received feedback from plan sponsors and other stakeholders that there should be more certainty in the timeframe applied to the exceptions process. We are seeking to balance the importance of the plan receiving the prescriber's supporting statement so that a thorough decision may be made on the request and having a standard maximum time for notifying an enrollee of an exception request decision. We believe greater certainty in the exceptions process will be beneficial to enrollees and plans. Establishing a fixed period in which the plan must render a decision on an exception request may also have the effect of more timely submission of supporting statements by prescribers once they become familiar with the fixed timeframe in which plans must issue a decision on an exception request. To that end, we are proposing to amend §§ 423.568(b), 423.570(d)(1) and 423.572(a) to state that, for an exception request, the plan must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its decision no later than 72 hours (or 24 hours in the case of an expedited decision) of receipt of the prescriber's supporting statement or 14 calendar days after receipt of the request, whichever occurs first. Consistent with existing regulations, the plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its decision on an exception request no later than 72 hours (or 24 hours in the case of an expedited decision) after receiving the prescriber's supporting statement. We are not proposing a change to the existing timeframes for issuing decisions, except that we are proposing an outside limit to the timeframe to address instances in which a prescriber's supporting statement is not timely received. The proposed change limits the timeframe for notifying the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of the decision to no later than 14 calendar days following receipt of the request. In other words, in cases where the plan does not receive a prescriber supporting statement (or does not receive it timely) it must notify the enrollee (and prescriber, as appropriate) of its decision no later than 14 calendar days from the receipt of the request. For example, if the plan sponsor receives the prescriber's supporting statement late in the adjudication time period (for example, on the 12th day), the plan sponsor would still be required to notify the enrollee of its decision no later than 14 calendar days from the receipt of the request. We understand that a supporting statement that is received late in the adjudication time period may mean the plan sponsor has less time to conduct its review, but we believe this circumstance is mitigated by the value in having greater certainty in the process by establishing a maximum timeframe for notifying the enrollee of the plan sponsor's decision. If the plan sponsor does not have clinical support to approve the exception request, the plan will issue the standardized denial notice and explain in specificity the reason for the denial, the documentation needed to approve coverage of the

requested drug, and the enrollee's right to request an appeal. We believe this proposed approach affords the plan sponsor a reasonable period of time to obtain the prescriber's supporting statement while establishing greater certainty in the time period in which the enrollee will receive a decision on an exception request. If the enrollee is dissatisfied with the decision, the enrollee has the right to request an appeal. We invite comments on this proposal.

C. Clarifying Program Integrity Policies

1. Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE

a. Background

In the April 2018 final rule, we removed several requirements pertaining to MA and Part D provider and prescriber enrollment. One requirement, outlined in § 423.120(c)(6), stated that for a prescription to be eligible for coverage under the Medicare Part D program, the prescriber must have: (1) An approved enrollment record in the Medicare fee-for-service program; or (2) a valid opt-out affidavit on file with a Part A/Part B Medicare Administrative Contractor (A/B MAC). A second requirement, outlined in § 422.222, stated that providers that furnish health care items or services to a Medicare enrollee who receives his or her Medicare benefit through an MA organization must be enrolled in Medicare and be in an approved status no later than January 1, 2019. (The removal of these requirements had been proposed in a proposed rule that appeared in the **Federal Register** on November 28, 2017, titled ''Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program'' (82 FR 56336) (hereafter referred to as the November 2017 proposed rule)).

The overall purpose of Medicare provider enrollment is to prevent fraud, waste, and abuse, and to protect Medicare beneficiaries, by allowing CMS to carefully screen all providers and suppliers (especially those that potentially pose an elevated risk to Medicare) to confirm that they are qualified to furnish, order, certify, refer, or prescribe Medicare items, services, or drugs. The previously mentioned Part D and MA enrollment provisions would have supplemented our longstanding requirements, outlined in 42 CFR part 424, subpart P that all providers and suppliers that furnish Part A or B Medicare items or services enroll in Medicare.

During our preparations to implement the Part D and MA enrollment provisions by the January 1, 2019 effective date, several provider organizations expressed concerns about our forthcoming requirements. Regarding Part D, stakeholders expressed concerns that (1) most prescribers pose no risk to the Medicare program, (2) certain types of physicians and eligible professionals prescribe Part D drugs only very infrequently, and (3) the burden to the prescriber community would outweigh the program integrity benefits of the Part D enrollment requirement. Regarding MA, some stakeholders were concerned about the burden of having to enroll in Medicare, particularly considering that health care providers in MA organization networks that would have to enroll in Medicare must also undergo credentialing by their respective health plans. While enrolling such prescribers and providers gives Medicare a greater degree of scrutiny in determining a prescriber's or provider's qualifications, we noted in the April 2018 final rule that the perceived burden associated with this process could cause some prescribers and providers not to enroll in Medicare, thus possibly leading to access to care issues if such providers left MA networks as a result. As of early 2018, approximately 420,000 Part D prescribers and 120,000 MA providers remained unenrolled in Medicare.

Given these concerns, we stated in the April 2018 final rule our belief that the best means of reducing the burden of the Part D and MA enrollment requirements without compromising our payment safeguard objectives would be to focus on prescribers and providers that pose an elevated risk to Medicare beneficiaries and the Trust Funds. That is, rather than require the enrollment of Part D prescribers and MA providers regardless of the level of risk they might pose, we would prohibit payment for Part D drugs and MA items or services that are, as applicable, prescribed or furnished by demonstrably problematic prescribers and providers. Therefore, we established in the April 2018 final rule a policy under which: (1) Such problematic parties would be placed on a ''preclusion list''; and (2) payment for Part D drugs and MA services and items prescribed or furnished by these individuals and entities would be rejected or denied, as applicable.

For purposes of this proposed rule, the most pertinent policies we finalized in the April 16, 2018 rule included the following:

- In § 423.100 (for Part D) and § 422.2 (for MA), we stated that the term ''preclusion list'' means a CMS-compiled list of, as applicable, prescribers and providers that:

++ Meet all of the following requirements:

++ The individual or entity is currently revoked from the Medicare program under § 424.535.

++ The individual or entity is currently under a reenrollment bar under § 424.535(c).

++ CMS determines that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program. In making this determination under this paragraph, CMS considers the following factors:

—The seriousness of the conduct underlying the individual's or entity's revocation.

—The degree to which the individual's or entity's conduct could affect the integrity of the Part D or MA program.

—Any other evidence that CMS deems relevant to its determination; or

++ Meet both of the following requirements:

++ The individual or entity has engaged in behavior for which CMS could have revoked the individual or entity to the extent applicable if they had been enrolled in Medicare.

++ CMS determines that underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program. In making this determination under this paragraph, CMS considers the following factors:

—The seriousness of the conduct underlying the individual's or entity's revocation.

—The degree to which the individual's or entity's conduct could affect the integrity of the Part D or MA program.

—Any other evidence that CMS deems relevant to its determination.

- We revised and added various provisions in 42 CFR part 498, subpart A, that permitted individuals and entities to appeal their inclusion on the preclusion list. Specifically:

++ We added a new paragraph (20) to § 498.3(b) stating that a CMS determination to include an individual or entity on the preclusion list constitutes an initial determination.

++ In § 498.5, we added a new paragraph (n) containing the following provisions:

—In paragraph (n)(1), we stated that any individual or entity dissatisfied with an initial determination or revised initial determination that they are to be included on the preclusion list may request a reconsideration in accordance with § 498.22(a).

—In paragraph (n)(2), we stated that if CMS or the individual or entity under paragraph (n)(1) is dissatisfied with a reconsidered determination under paragraph (n)(1), or a revised reconsidered determination under § 498.30, CMS or the individual or entity is entitled to a hearing before an administrative law judge (ALJ).
—In paragraph (n)(3), we stated that if CMS or the individual or entity under paragraph (n)(2) is dissatisfied with a hearing decision as described in paragraph (n)(2), CMS or the individual or entity may request review by the Departmental Appeals Board (DAB) and the individual or entity may seek judicial review of the DAB's decision.

• In § 423.120(c)(6)(v) (for Part D) and § 422.222(a)(2) (for MA), we stated that CMS would send written notice to the individual or entity via letter of their inclusion on the preclusion list. The notice would contain the reason for said inclusion and would inform the individual or entity of their appeal rights. We further stated that the affected party could appeal their inclusion on the preclusion list in accordance with Part 498.

• We stated in § 423.120(c)(6)(iv)(A) that a Part D sponsor or its Pharmacy Benefit Manager (PBM) must not reject a pharmacy claim or request for reimbursement for a Part D drug unless the sponsor has provided the written notice to the beneficiary described in § 423.120(c)(6)(iv)(B). Under paragraph (iv)(B), the Part D sponsor or its PBM must:

++ Provide an advance written notice to any beneficiary who has received a prescription from a prescriber on the preclusion list as soon as possible but to ensure that the beneficiary receives the notice no later than 30 days after the publication of the most recent preclusion list; and

++ Ensure that reasonable efforts are made to notify the prescriber of a beneficiary who was sent a notice under paragraph (iv)(B).

• We stated in the preamble to the April 2018 final rule that individuals and entities would only be placed on the preclusion list upon exhausting their first level of appeal.

• In the preamble to the previously mentioned November 2017 proposed rule (82 FR 56446), we stated that if a beneficiary's access to a service, item, or drug is denied because of the application of the preclusion list to his or her prescriber or provider, the beneficiary would be permitted to appeal alleged errors in applying the preclusion list. However, in the April 2018 final rule (83 FR 16660), we stated that if payment is denied because the prescriber or provider is on the preclusion list, the beneficiary would not have the right to appeal.

• We stated in April 2018 final rule (83 FR 16642) that an unenrolled individual or entity would remain on the preclusion list for the same length of time as the reenrollment bar that we could have imposed on the individual or entity had they been enrolled in Medicare and then revoked.

In addition, we stated that the preclusion list provisions in the April 2018 final rule (83 FR 16440) were to become effective on January 1, 2019.

b. Proposed Changes

For reasons stated in this section III.C.1.b. of this proposed rule, we propose to make changes to several of the preclusion list policies outlined in the April 2018 final rule.

(1) Appeals Process for Individuals and Entities on the Preclusion List

Similar to individuals and entities that are placed on the preclusion list, providers and suppliers whose Medicare enrollment is revoked for one or more of the revocation reasons described in § 424.535 (for example, the provider submitted false information to Medicare, has engaged in abusive prescribing of Part D drugs, or is excluded by the Office of Inspector General (OIG)) may appeal such revocation under § 498.5(l). Under § 498.22(b)(3), the provider or supplier has 60 days from receipt of the notice of revocation from CMS or its contractor to request a reconsideration, which is considered the first level of appeal. CMS has 90 days to render its reconsideration decision and to notify the provider or supplier thereof.

As already mentioned, under § 423.100 (for Part D) and § 422.2 (for MA), an individual or entity may be placed on the preclusion list if their Medicare enrollment is revoked, the individual or entity is currently under a reenrollment bar, and CMS determines that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program. Having stated in the April 2018 final rule (83 FR 16662) that individuals and entities would only be placed on the preclusion list upon exhausting their first level of appeal, we are concerned that there could be a very lengthy delay before the individual or entity is actually placed on said list. This is because the individual or entity, under existing regulations, would be able to first appeal their revocation and, if unsuccessful, could next appeal their placement on the preclusion list because of the revocation. Consider the following example:

• A provider receives a revocation notice on March 1.

• The provider has until April 30 (or 60 days) to file a request for reconsideration.

• CMS has until July 29 (or 90 days) to render its reconsideration decision.

• CMS sends notice of its denial of the provider's reconsideration on July 29, at which point the revoked provider has until September 28 (or 60 days from the date of the notice) to now request a reconsideration of its inclusion on the preclusion list.

• The provider requests a reconsideration of its inclusion on the preclusion list on September 28.

• CMS has until December 27 (or 90 days) to render its reconsideration decision.

• CMS sends notice of its denial of the provider's reconsideration on December 27.

• With the first level of appeal completed, the provider is placed on the preclusion list.

The end result of this process is that it could take up to nearly 9 months before a provider is placed on the preclusion list, meaning that, for instance, a prescriber who was revoked for a felony conviction could continue to prescribe covered Part D drugs for an extended period before placement on the preclusion list results in a prohibition against payment by a Part C plan, Medicare cost plan, Part D plan, or PACE organization to the prescriber (for any health care services furnished) for the prescribed drug. This is inconsistent with the principal goal of the preclusion list, which is to prevent payment for Part D drugs or MA services or items prescribed or furnished, as applicable, by problematic parties. Such a lengthy delay could place Medicare beneficiaries and the Trust Funds at risk.

We believe that an appropriate balance can be found between preserving a prescriber's or provider's appeal rights and ensuring that problematic parties are placed on the preclusion list as soon as feasible. To facilitate this objective, we propose several regulatory changes that would consolidate the revocation and preclusion list appeals processes so that they run concurrently, rather than consecutively. This means, in effect, that if a prescriber or provider is to be placed on the preclusion list in conjunction with a revocation under § 424.535, no more than 5 months would expire before the preclusion list inclusion occurs. Though we recognize

that 5 months is not an inconsiderable length of time, it would be preferable to the previously referenced 9-month period while still ensuring that affected prescribers and providers have an opportunity to be heard.

The specific regulatory revisions we propose regarding this issue are as follows:

• In § 423.120(c)(6)(v), we propose to:

++ Consolidate the existing version of paragraph (v) into a revised § 423.120(c)(6)(v)(A).

++ Establish a new § 423.120(c)(6)(v)(B) stating that in situations where the prescriber's inclusion on the preclusion list is based on a contemporaneous Medicare revocation under § 424.535:

—The notice described in paragraph (c)(6)(v)(A) must also include notice of the revocation, the reason(s) for the revocation, and a description of the prescriber's appeal rights concerning the revocation.

—The appeals of the prescriber's inclusion on the preclusion list and the prescriber's revocation shall be filed jointly by the prescriber and, as applicable, considered jointly by CMS under 42 CFR part 498.

• In § 422.222(a)(2), we propose to do the following:

++ Move the existing version of this paragraph into a new § 422.222(a)(2)(i).

++ Establish a new § 422.222(a)(2)(ii) stating that in situations where the individual's or entity's inclusion on the preclusion list is based on a contemporaneous Medicare revocation under § 424.535:

—The notice described in paragraph (a)(2)(i) must also include notice of the revocation, the reason(s) for the revocation, and a description of the individual's or entity's appeal rights concerning the revocation.

—The appeals of the individual's or entity's inclusion on the preclusion list and the individual's or entity's revocation shall be filed jointly by the individual or entity and, as applicable, considered jointly by CMS under 42 CFR part 498.

• In § 498.5(n)(1), we propose to do the following:

++ Move the existing version of this paragraph to a new § 498.5(n)(1)(i).

++ Establish a new § 498.5(n)(1)(ii)(A) stating that in situations where the individual's or entity's inclusion on the preclusion list is based on a Medicare revocation under § 424.535 and the individual or entity receives contemporaneous notice of both actions, the individual or entity may request a joint reconsideration of both the preclusion list inclusion and the revocation in accordance with § 498.22(a).

++ Establish a new § 498.5(n)(1)(ii)(B) stating that the individual or entity may not submit separate reconsideration requests under paragraph (ii)(A) for inclusion on the preclusion list or a revocation if the individual or entity received contemporaneous notice of both actions.

We believe these changes would clarify our expectations and the program procedures concerning the filing of appeals when a party's placement on the preclusion list is based on a Medicare revocation. We also stress that our proposed appeals consolidation would not affect appeals of OIG exclusions, which are handled through a separate process outlined in the applicable OIG regulations.

(2) Timing of Addition to the Preclusion List

Although, as mentioned previously, we stated in the April 2018 final rule (83 FR 16662) that prescribers and providers would only be placed on the preclusion list upon exhausting their first level of appeal, we did not include this language in the regulatory text. We propose to do so in this proposed rule to reiterate our position on this important issue. We believe that fairness warrants that the affected prescriber or provider have an opportunity to be heard before being included on the preclusion list. Therefore, we propose in new § 423.120(c)(6)(v)(C)(*1*) (for Part D) and new § 422.222(a)(3)(i) (for MA) that, respectively, a prescriber or provider would only be included on the preclusion list after the expiration of either of the following:

• If the prescriber or provider does not file a reconsideration request under § 498.5(n)(1), the prescriber or provider will be added to the preclusion list upon the expiration of the 60-day period in which the prescriber or provider may request a reconsideration.

• If the prescriber or provider files a reconsideration request under § 498.5(n)(1), the prescriber or provider will be added to the preclusion list effective on the date on which CMS, if applicable, denies the prescriber's or provider's reconsideration.[22]

However, we also believe that an exception to these proposed policies is necessary for preclusion list inclusions that are based on an OIG exclusion. This is because section 1862(e) of the Act (42 U.S.C. 1395y(e)) is clear that no federal health care program payment may be made for any items or services furnished by an excluded individual or entity, or directed or prescribed by an excluded physician. We believe that a failure to add an excluded provider or prescriber to the preclusion list until the expiration of the applicable time periods in § 423.120(c)(6)(v)(C)(*1*) (for Part D) and § 422.222(a)(3)(i) (for MA) would be inconsistent with section 1862(e) of the Act. Accordingly, we propose in new § 423.120(c)(6)(v)(C)(*2*) (for Part D) and § 422.222(a)(3)(ii) (for MA) that an excluded prescriber or provider would be added to the preclusion list effective on the date of the exclusion.

(3) Effective Date

We propose that, with one exception, the preclusion list regulatory revisions and additions addressed in this proposed rule would become applicable to MA organizations (and cost plans and PACE organizations by virtue of cross-references in parts 417 and 460 to the MA part 422 regulation) and Part D plans on January 1, 2020. Considering the need to ensure that stakeholders have as much time as possible to prepare for these revisions and additions, we believe that a January 1, 2020 effective date is appropriate. However, we also propose that the effective date of our previously mentioned consolidated appeals provisions in §§ 423.120(c)(6)(v), 422.222(a)(2), and § 498.5(n)(1) would be 60 days after their publication in a final rule. As discussed in section C.1.b.(1) above, it is important that problematic providers be placed on the preclusion list as soon as possible; for this reason, we believe it would be inconsistent with CMS' program integrity objectives to wait until January 1, 2020 to implement our consolidated appeals provisions. We also solicit public comments on whether some or all of our other proposed preclusion list provisions discussed in this section III.C.1. of this proposed rule should become effective and applicable beginning 60 days after the publication date of this proposed rule.

We note that the January 1, 2019 preclusion list effective date identified in the April 2018 final rule remains in place, and the preclusion list provisions finalized in that rule will continue to be implemented on January 1, 2019.

[22] In the April 2018 final rule, we adopted cross-references in 42 CFR parts 417 and 460 to Part 422 so that our MA preclusion list provisions in that rule would also apply to, respectively, cost plans (Part 417) and PACE organizations (Part 460). Consistent with said cross-references, our MA preclusion list provisions in this proposed rule would similarly apply to cost plans and PACE organizations.

(4) Claim Denials and Beneficiary Notification

We stated in the April 2018 final rule (83 FR 16440) that, upon CMS' publication of the first preclusion list, once a prescriber or provider is added to such initial list after the completion of their first level of appeal, claims would not be impacted for a 90-day period thereafter (82 FR 16667). We explained that this 90-day period would include—(1) a 30-day period for the plans and MA organizations to intake the preclusion list data; and (2) a 60-day period in which the plan or MA organization would (a) notify the beneficiary of the prescriber's or provider's preclusion and (b) work to transition the beneficiary to a new prescriber or provider. Once this 90-day period expires, claim denials would commence.

The purpose of this policy was to give Part D plans and MA organizations additional time immediately following the January 1, 2019 effective date to accustom themselves to the preclusion list process and file layout. We also believed that beneficiaries should be given advance notice that, as applicable, certain Part D drugs and MA services and items they receive as patients of the precluded prescriber or provider would no longer be covered as of the expiration of the 90-day period. However, we emphasized that all subsequent updates to the preclusion list, that is, all updates after the release of the initial preclusion list—would not require the expiration of a 90-day period before claims were denied. There were two reasons for this. First, we did not believe that the plans and MA organizations would need the aforementioned 30-day period any longer, for they would have become better acclimated to the operational aspects of the preclusion list process. Second, since most of the parties included on the initial preclusion list would remain on it in subsequent updates and, accordingly, affected beneficiaries would already have received notice of their prescriber's or provider's appearance on the initial preclusion list, we did not believe that repeated, monthly notices to beneficiaries thereafter would be warranted. As such, for subsequent preclusion list updates, claim denials would begin effective upon the date the prescriber or provider was included on the preclusion list, which, as indicated previously, would be that specified in revised § 423.120(c)(6)(v) and new § 422.222(a)(3).

Upon further consideration, we are concerned that beneficiaries whose prescribers and providers are added to subsequent updates to the preclusion list would not receive any notice of those additions nor of the consequences of placement of such providers and prescribers on the preclusion list. This could greatly impede the ability of enrollees to obtain needed services, items, or drugs for an extended period of time; indeed, by the time a beneficiary learns of his or her prescriber's or provider's inclusion on the preclusion list (through, for instance, receipt of a claim denial) and he or she thereafter manages to find a new prescriber or provider, many months could elapse. We believe that such situations must be avoided and, to that end, that the previously mentioned notification requirement and delayed denial of claims for the initial preclusion list should apply to each subsequent update as well. Accordingly, we propose that claim denials for preclusion list updates, beginning in 2020, would occur consistent with the following timeframes listed below (although we would recommend that plans implement these timeframes for any updates to the preclusion list posted in 2019 subsequent to the initial preclusion list):

- Upon the posting of the updated preclusion list, the Part D sponsor or MA organization would be required to send notice to the beneficiary that his or her prescriber or provider has been added to preclusion list within 30 days of the posting of the updated preclusion list. We believe a 30-day period is necessary to allow the plans to carefully review the preclusion list updates to identify new or removed prescribers or providers, make any applicable operational adjustments, and send notices to beneficiaries whose prescribers or providers are now on the preclusion list.
- Beginning 60 days after sending the beneficiary notice(s) described in the previous paragraph, the plan sponsor or MA organization would deny the prescriber's or provider's prescriptions or claims. This 60-day period would give beneficiaries time to locate another prescriber or provider from whom they can receive Part D prescriptions or MA services and items.

With these timeframes, therefore, a total period of 60 to 90 days (depending chiefly on when the beneficiary notification is sent) would elapse between the date on which the preclusion list update is posted and the date on which claims denials would begin. We recognize that applying this 60- to 90-day period to subsequent updates (rather than exclusively to the initially posted list) could result in a precluded prescriber or provider being permitted to continue treating Part D and MA beneficiaries for several months without their Part D prescriptions or MA claims being denied. However, we believe that the prevention of potentially serious dangers to the health and safety of Medicare beneficiaries that could ensue if they are without crucial medications for an extended period must take precedence.

Although, as already mentioned, we discussed the delayed claim denial period in the April 2018 final rule (83 FR 16441), we did not incorporate this policy into the regulatory text. Further, while § 423.120(c)(6) contains certain provisions regarding preclusion list beneficiary notification, there are no such concomitant provisions for MA in § 422.222. Thus, we propose to make the following revisions and additions, as applicable, to § 423.120(c)(6) and § 422.222 in this proposed rule in order to incorporate our beneficiary notification proposals:

- Section 422.222 would be revised as follows:

++ Existing paragraph (a)(1) would be moved to a new paragraph (a)(1)(i) that would state: ''Except as provided in paragraph (a)(1)(ii) of this section, an MA organization must not make payment for a health care item or service furnished by an individual or entity that is included on the preclusion list, defined in § 422.2.''

++ New paragraph (a)(1)(ii) would state: ''With respect to MA providers that have been added to an updated preclusion list, the MA organization must do all of the following:''

++ New paragraph (a)(1)(ii)(A) would state: ''No later than 30 days after the posting of this updated preclusion list, must provide an advance written notice to any beneficiary who has received an MA service or item from the individual or entity added to the preclusion list in this update.''

++ New paragraph (a)(1)(ii)(B) would state: ''Must ensure that reasonable efforts are made to notify the individual or entity described in paragraph (a)(1)(ii) of this section of a beneficiary who was sent a notice under paragraph (a)(1)(ii)(A) of this section; and''

++ New paragraph (a)(1)(ii)(C) would state: ''Must not deny payment for a service or item furnished by the newly added individual or entity, solely on the ground that they have been included in the updated preclusion list, in the 60-day period after the date it sent the notice described in paragraph (a)(1)(ii)(A) of this section.''

Under the MA regulation at 42 CFR 422.224, MA organizations are prohibited from paying individuals and entities that are on the CMS preclusion

list. We understand that this language includes both contracted and non-contracted parties; therefore, this prohibition against paying precluded individuals and entities would include contracted and non-contracted parties for purposes of the provisions in § 422.222(a)(1), for we believe it is necessary to ensure that the scope of the payment prohibition in the latter section aligns with that already established in § 422.224. Further, we believe that applying this requirement to both contracted and non-contracted parties better safeguards our beneficiaries while also increasing consistency by aligning with the OIG exclusion process, which is also applied to both contracted and non-contracted parties.

Consistent with our proposed changes to § 422.222(a)(1), we propose to delete the existing structure of § 423.120(c)(6)(iv), which we cited previously, and replace it with the following:

++ A new opening paragraph of (c)(6)(iv) would state:

''With respect to Part D prescribers that have been added to an updated preclusion list, the Part D plan sponsor must do all of the following:''

++ Revised paragraph (c)(6)(iv)(A) would state: ''Subject to all other Part D rules and plan coverage requirements, and no later than 30 days after the posting of this updated preclusion list, must provide an advance written notice to any beneficiary who has received a Part D drug prescribed by a prescriber added to the preclusion list in this update.''

++ Revised paragraph (c)(6)(iv)(B) would state: ''Must ensure that reasonable efforts are made to notify the prescriber described in paragraph (c)(6)(iv) of this section of a beneficiary who was sent a notice under paragraph (c)(6)(iv)(A) of this section; and''

++ New paragraph (c)(6)(iv)(C) would state: ''Must not reject a pharmacy claim or deny beneficiary request for reimbursement for a Part D drug prescribed by the prescriber, solely on the ground that they have been included in the updated preclusion list, in the 60-day period after the date it sent the notice described in paragraph (c)(6)(iv)(A) of this section.''

For providers and prescribers that are both on the preclusion list and excluded by the OIG, the aforementioned beneficiary notification process would not be intended to replace or supplant any existing OIG processes for notifying beneficiaries of excluded providers or prescribers.

(5) Beneficiary Appeals

We mentioned earlier that in the preamble to the April 2018 final rule, we stated that if payment is denied because the prescriber or provider is on the preclusion list, the affected beneficiary would not have the right to appeal that denial. However, we did not include accompanying regulatory text in the final rule. To remedy this, we propose to add new § 423.120(c)(6)(viii) and § 422.222(a)(4) stating that payment denials based upon, respectively, a prescriber's or provider's inclusion on the preclusion list are not appealable by beneficiaries.

(6) Felony Convictions

We proposed in the November 2017 proposed rule to keep unenrolled prescribers and providers on the preclusion list for the same length of time as the reenrollment bar that we could have imposed on the prescriber or provider had they been enrolled and then revoked. While this policy was finalized in the April 2018 final rule, it was not included in the regulatory text. Given this, we propose several regulatory revisions.

First, we propose to revise the definitions of ''preclusion list'' in §§ 423.100 and 422.2. The current definitions contain two general categories of parties that could be included on the preclusion list—(1) prescribers and providers that are currently revoked from Medicare and are under a reenrollment bar; and (2) prescribers and providers that have engaged in behavior for which CMS could have revoked the prescriber or provider to the extent applicable had they been enrolled in Medicare. Although these two categories encompass felony convictions, we believe that the severity of felonious behavior warrants the establishment of a third category that is specific to felony convictions. Therefore, we propose to remove felony convictions from the scope of the first two categories, with the new third category covering prescribers and providers—regardless of whether they are or were enrolled in Medicare—that have been convicted of a felony under federal or state law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program; we note that this language is consistent with that in the current version of § 424.535(a)(3), which permits CMS to revoke a provider's or supplier's enrollment based on a federal or state felony conviction within the past 10 years. Recognizing, however, that the facts of each case are different and must be judged on their own merits, we propose that CMS would first consider the following factors before determining whether a prescriber's or provider's inclusion on the preclusion list is warranted under our new proposed third category for felony convictions: (1) The severity of the offense; (2) when the offense occurred; and (3) any other information that CMS deems relevant to its determination. We also acknowledge that with the expansion of the number of preclusion list categories from two to three, we must, and propose to, add an ''or'' to the regulatory text immediately after the second category in the preclusion list definitions. This would clarify that a prescriber or provider need only come within the purview of one of the three categories to be included on the preclusion list.

Second, we propose to establish new §§ 423.120(c)(6)(vii) and 422.222(a)(5) that would codify, clarify, and expand upon the previously mentioned policy concerning the length of a prescriber's or provider's inclusion on the preclusion list:

- In §§ 423.120(c)(6)(vii)(A) and 422.222(a)(5)(i), we propose that, except as provided in §§ 423.120(c)(6)(vii)(C) and (D) and 422.222(a)(5)(iii) and (iv), revoked prescribers and providers, respectively, would be included on the preclusion list for the same length of time as the prescriber's or provider's reenrollment bar. This would be consistent with our intended, though uncodified, policy in the April 2018 final rule (83 FR 16441).
- In §§ 423.120(c)(6)(vii)(B) and 422.222(a)(5)(ii), we propose that, except as provided in §§ 423.120(c)(6)(vii)(C) and (D) and 422.222(a)(5)(iii) and (iv), unenrolled prescribers and providers, respectively, would be included on the preclusion list for the same length of time as the reenrollment bar that we could have imposed on the prescriber or provider had they been enrolled and then revoked. This would codify the previously mentioned policy concerning the period of time that unenrolled providers and suppliers would remain on the preclusion list.
- In §§ 423.120(c)(6)(vii)(C) and 422.222(a)(5)(iii), we propose that, except as provided in §§ 423.120(c)(6)(vii)(D) and 422.222(a)(5)(iv), prescribers and providers—regardless of whether they are or were enrolled in Medicare—that are included on the preclusion list because of a felony conviction will remain on the preclusion list for a 10-year period, beginning on the date of the felony conviction, unless CMS determines that a shorter time length of

time is warranted. Factors that we would consider in making such a determination would be: (1) The severity of the offense; (2) when the offense occurred; and (3) any other information that CMS deems relevant to its determination.

We believe that the seriousness of certain types of felonious behavior could, in some cases, warrant the prescriber's or provider's inclusion on the preclusion list for a very lengthy period of time. Indeed, we recognized this in a proposed rule published in the **Federal Register** on March 1, 2016 titled ''Medicare, Medicaid, and Children's Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process'' (81 FR 10720). We proposed in this proposed rule to extend the maximum reenrollment bar under § 424.535(c) from 3 years to 10 years so that the Medicare program, the Medicare Trust Funds, and beneficiaries could be protected from providers that engaged in especially egregious activities, including felonies. To ensure such protections, we believe that a maximum 10-year preclusion list period for felony convictions is justified. Conversely, because certain felonies may not warrant a 10-year inclusion on the preclusion list, we believe that certain factors, as already described, should be weighed in determining the applicable timeframe.

We emphasize that because our proposed preclusion list period for felonious prescribers and providers would begin on the date of the conviction, such parties may be included on the preclusion list for less than 10 years even if CMS imposes the full 10-year period. To illustrate, assume that a physician is convicted of a felony on January 2, 2020. CMS imposes a 10-year preclusion list period, and he is added to the preclusion list on June 2, 2020. Because the 10-year period commences on the date of the conviction (January 2, 2020), the physician would only be on the preclusion list for 9 years and 6 months.

The OIG in many cases excludes providers and prescribers for a period that is longer than the period permitted for a reenrollment bar under § 424.535(c). As discussed previously, section 1862(e) of the Act is clear that no federal health care program payment may be made for any items or services furnished by an excluded individual or entity, or directed or prescribed by an excluded physician. We believe that CMS should keep an excluded provider or prescriber on the preclusion list at least until the provider or prescriber has been reinstated by the OIG in order to be consistent with section 1862(e) of the Act. Consequently, we propose in new § 423.120(c)(6)(vii)(D) and 422.222(a)(5)(iv) that in cases where a prescriber or provider is excluded by the OIG, the prescriber or provider remains on the preclusion list until the expiration of the CMS-imposed preclusion list period or reinstatement by the OIG, whichever occurs later.

(7) Beneficiary Liability

During the notice and comment period for the November 2017 proposed rule (82 FR 16664), we received a comment recommending that in CMS' implementation of the preclusion list, the beneficiary should be held harmless unless the beneficiary engaged in fraudulent activity. We interpreted this comment to be, in the context of MA, that the beneficiary should not be held financially liable if the MA provider that furnished to him or her the service or item in question is on the preclusion list. We generally agreed with this, noting in our response to said comment:

- The contract provisions required between the MA plan and a network provider in accordance with § 422.504(g)(1)(iii) are binding on providers. Such agreements specify that Qualified Medicare Beneficiary (QMB) programs must not be charged cost sharing when the state is responsible for paying such amounts under the Medicaid program.
- Section 422.504(g) contains broader beneficiary protection requirements for MA organizations. This includes a requirement that the plan must indemnify the beneficiary from any fees that are the legal obligation of the MA organization for services furnished by providers that do not contract, or that have not otherwise entered into an agreement, with the MA organization, to provide services to the organization's enrollees.

Section 422.504 outlines provisions that a contract between an MA organization and CMS must contain. Paragraph (g) thereof outlines requirements to which the MA organization must agree; under paragraph (g)(1), each MA organization must adopt and maintain arrangements satisfactory to CMS to protect its enrollees from incurring liability (for example, as a result of an organization's insolvency or other financial difficulties) for payment of any fees that are the legal obligation of the MA organization. To implement our overall position as it pertains to the preclusion list, we believe that a specific addition to § 422.504(g)(1) is necessary. Consistent with our existing authority under section 1857(e)(1) of the Act, we thus propose to add a new paragraph (g)(1)(iv) to § 422.504 under which the MA organization agrees that the enrollee must not have any financial liability for services or items furnished to the enrollee by an MA contracted individual or entity on the preclusion list, as defined in § 422.2 and as described in § 422.222. We acknowledge that the effect of this provision would be limited to providers under contract with the MA organization, for we believe this is consistent with the general applicability and scope of § 422.504 and the ability of the MA organization to control or impose requirements on the health care providers that furnish covered services and items to enrollees. Nonetheless, we believe that proposed paragraph (g)(1)(iv) would help financially protect beneficiaries from problematic providers as well as codify the previously mentioned position we expressed in the preamble of the April 2018 final rule (83 FR 16646) but did not address in the regulatory text.

(8) Technical Correction Concerning the Term ''Individual'' (§ 423.120(c)(6))

We also propose to make technical changes to § 423.120(c)(6)(i), (ii), (iii), and (vi). These paragraphs state as follows, respectively:

- Except as provided in paragraph (c)(6)(iv) of this section, a Part D sponsor must reject, or must require its PBM to reject, a pharmacy claim for a Part D drug if the individual who prescribed the drug is included on the preclusion list, defined in § 423.100.
- Except as provided in paragraph (c)(6)(iv) of this section, a Part D sponsor must deny, or must require its PBM to deny, a request for reimbursement from a Medicare beneficiary if the request pertains to a Part D drug that was prescribed by an individual who is identified by name in the request and who is included on the preclusion list, defined in § 423.100.
- A Part D plan sponsor may not submit a prescription drug event (PDE) record to CMS unless it includes on the PDE record the active and valid individual NPI of the prescriber of the drug, and the prescriber is not included on the preclusion list, defined in § 423.100, for the date of service.
- CMS has the discretion not to include a particular individual on (or if warranted, remove the individual from) the preclusion list should it determine that exceptional circumstances exist regarding beneficiary access to prescriptions.

Because some states permit pharmacies to prescribe medications, we believe that the use of the term ''individual'' in paragraphs (i), (ii), (iii), and (vi) is too restrictive. We therefore

propose in paragraphs (i), (ii), and (vi) to change this term to ''prescriber'' so as to clarify that the prescriber need not be an individual. In a similar vein, we propose:

• In § 423.120(c)(6)(iii) to change the phrase ''individual NPI of the prescriber'' to ''NPI of the prescriber'', and

• In paragraph (2)(i) of the definition of ''preclusion list'' in § 423.100 (and as reflected in our previously discussed proposal to revise this paragraph (see section II.C.1.b.6. of this proposed rule)) to change the phrase ''he or she'' to ''prescriber.''

(9) Proposed Provisions

Given the foregoing, we propose the following changes:

• We would revise the definition of ''preclusion list'' in § 422.2 as follows:

++ Paragraph (1)(i) of the definition would be changed from ''the individual or entity is currently revoked from Medicare under § 424.535'' to ''the individual or entity is currently revoked from Medicare for a reason other than that stated in § 424.535(a)(3) of this chapter.''

++ Paragraph (2)(i) of the definition would be changed from ''the individual or entity has engaged in behavior for which CMS could have revoked the individual or entity to the extent applicable had they been enrolled in Medicare'' to ''the individual or entity has engaged in behavior, other than that described in § 424.535(a)(3) of this chapter, for which CMS could have revoked the individual or entity to the extent applicable had they been enrolled in Medicare.''

++ We would add the word ''or'' to the end of paragraph (2)(ii)(C) of the definition.

++ New paragraph (3) would read as follows: ''The individual or entity, regardless of whether they are or were enrolled in Medicare, has been convicted of a felony under federal or state law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program. Factors that CMS considers in making such a determination under this paragraph are: (1) The severity of the offense; (2) when the offense occurred; and (3) any other information that CMS deems relevant to its determination.''

• We would revise § 422.222 such that it would read as follows:

++ Existing paragraph (a)(1) would be moved to a new paragraph (a)(1)(i) that would state: ''Except as provided in paragraph (a)(1)(ii) of this section, an MA organization must not make payment for a health care item or service furnished by an individual or entity that is included on the preclusion list, defined in § 422.2.''

++ New paragraph (a)(1)(ii) would state: ''With respect to MA providers that have been added to an updated preclusion list, the MA organization must do all of the following:''

++ New paragraph (a)(1)(ii)(A) would state: ''No later than 30 days after the posting of this updated preclusion list, must provide an advance written notice to any beneficiary who has received an MA service or item from the individual or entity added to the preclusion list in this update;''

++ New paragraph (a)(1)(ii)(B) would state: ''Must ensure that reasonable efforts are made to notify the individual or entity described in paragraph (a)(1)(ii) of this section of a beneficiary who was sent a notice under paragraph (a)(1)(ii)(A) of this section; and

++ New paragraph (a)(1)(ii)(C) would state: ''Must not deny payment for a service or item furnished by the newly added individual or entity, solely on the ground that they have been included in the updated preclusion list, in the 60-day period after the date it sent the notice described in paragraph (a)(1)(ii)(A) of this section.''

++ In new § 422.222(a)(2)(i), we propose to incorporate therein the current version of § 422.222(a)(2).

++ New § 422.222(a)(2)(ii) would state: ''If the individual's or entity's inclusion on the preclusion list is based on a contemporaneous Medicare revocation under § 424.535 of this chapter:''.

++ New § 422.222(a)(2)(ii)(A) would state: ''The notice described in paragraph (a)(2)(i) of this section must also include notice of the revocation, the reason(s) for the revocation, and a description of the individual's or entity's appeal rights concerning the revocation.''

++ New § 422.222(a)(2)(ii)(B) would state: ''The appeals of the individual's or entity's inclusion on the preclusion list and the individual's or entity's revocation shall be filed jointly by the individual or entity and, as applicable, considered jointly by CMS under 42 CFR part 498 of this chapter.

++ New § 422.222(a)(3)(i) would state: ''Except as provided in paragraph (3)(ii), an individual or entity will only be included on the preclusion list after the expiration of either of the following:''.

++ New § 422.222(a)(3)(i)(A) would state: ''If the individual or entity does not file a reconsideration request under § 498.5(n)(1) of this chapter, the individual or entity will be added to the preclusion list upon the expiration of the 60-day period in which the individual or entity may request a reconsideration; or''.

++ New § 422.222(a)(3)(i)(B) would state: ''If the individual or entity files a reconsideration request under § 498.5(n)(1) of this chapter, the individual or entity will be added to the preclusion list effective on the date on which CMS, if applicable, denies the individual's or entity's reconsideration..''

++ New § 422.222(a)(3)(ii) would state: ''An OIG excluded individual or entity is added to the preclusion list effective on the date of the exclusion.

++ New § 422.222(a)(4) would state: ''Payment denials based upon an individual's or entity's inclusion on the preclusion list are not appealable by beneficiaries.''

++ New § 422.222(a)(5)(i) would state: ''Except as provided in paragraphs (a)(5)(iii) and (iv) of this section, an individual or entity that is revoked under § 424.535 of this chapter will be included on the preclusion list for the same length of time as the individual's or entity's reenrollment bar.''

++ New § 422.222(a)(5)(ii) would state: ''Except as provided in paragraphs (a)(5)(iii) and (iv) of this section, an individual or entity that is not enrolled in Medicare will be included on the preclusion list for the same length of time as the reenrollment bar that CMS could have imposed on the individual or entity had they been enrolled and then revoked.''

++ New § 422.222(a)(5)(iii) would state: ''Except as provided in paragraph (a)(5)(iv) of this section, an individual or entity, regardless of whether they are or were enrolled in Medicare, that is included on the preclusion list because of a felony conviction will remain on the preclusion list for a 10-year period, beginning on the date of the felony conviction, unless CMS determines that a shorter time length of time is warranted. Factors that CMS considers in making such a determination are: (A) The severity of the offense; (B) when the offense occurred; and (C) any other information that CMS deems relevant to its determination.''

++ New § 422.222(a)(5)(iv) would state: ''In cases where an individual or entity is excluded by the OIG, the individual or entity shall remain on the preclusion list until the expiration of the CMS-imposed preclusion list period or reinstatement by the OIG, whichever occurs later. ''

• New § 422.504(g)(1)(iv) would state that the MA organization agrees that the enrollee shall not have any financial liability for services or items furnished to the enrollee by an MA contracted individual or entity on the preclusion

list, as defined in § 422.2 and as described in § 422.222.

• We would revise the definition of ''preclusion list'' in § 423.100 as follows:

++ Revised paragraph (1)(i) of the definition would state: ''The prescriber is currently revoked from Medicare for a reason other than that stated in § 424.535(a)(3) of this chapter.''

++ Revised paragraph (2)(i) of the definition would state: ''The prescriber has engaged in behavior, other than that described in § 424.535(a)(3) of this chapter, for which CMS could have revoked the prescriber to the extent applicable had the prescriber been enrolled in Medicare.''

++ We would add the word ''or'' to the end of paragraph (2)(ii)(C) of the definition.

++ New paragraph (3) would state: ''The prescriber, regardless of whether the prescriber is or was enrolled in Medicare, has been convicted of a felony under federal or state law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program. Factors that CMS considers in making such a determination under this paragraph are: (i) The severity of the offense; (ii) when the offense occurred; and (iii) any other information that CMS deems relevant to its determination.''

• We would revise § 423.120(c)(6) as follows:

++ In paragraphs (c)(6)(i), (ii), and (vi), we would change the term ''individual'' to ''prescriber.''

++ In paragraph (iii), we would change the phrase ''individual NPI of the prescriber'' to ''NPI of the prescriber''.

++ A new opening paragraph of (c)(6)(iv) would state: ''With respect to Part D prescribers that have been added to an updated preclusion list, the Part D plan sponsor must do all of the following:''

++ Revised paragraph (c)(6)(iv)(A) would state: ''Subject to all other Part D rules and plan coverage requirements, and no later than 30 days after the posting of this updated preclusion list, must provide an advance written notice to any beneficiary who has received a Part D drug prescribed by a prescriber added to the preclusion list in this update;''

++ Revised paragraph (c)(6)(iv)(B) would state: ''Must ensure that reasonable efforts are made to notify the prescriber described in paragraph (c)(6)(iv) of this section of a beneficiary who was sent a notice under paragraph (c)(6)(iv)(A) of this section; and''

++ New paragraph (c)(6)(iv)(C) would state: ''Must not reject a pharmacy claim or deny a beneficiary request for reimbursement for a Part D drug prescribed by the prescriber, solely on the ground that they have been included in the updated preclusion list, in the 60-day period after the date it sent the notice described in paragraph (c)(6)(iv)(A) of this section.''

++ New § 423.120(c)(6)(v)(A) would state: ''CMS sends written notice to the prescriber via letter of their inclusion on the preclusion list. The notice must contain the reason for the inclusion on the preclusion list and inform the prescriber of their appeal rights. A prescriber may appeal their inclusion on the preclusion list under this section in accordance with part 498 of this chapter.''

++ New § 423.120(c)(6)(v)(B) would state: ''If the prescriber's inclusion on the preclusion list is based on a contemporaneous Medicare revocation under § 424.535 of this chapter:''.

++ New § 423.120(c)(6)(v)(B)(*1*) would state: ''The notice described in paragraph (c)(6)(v)(A) of this section must also include notice of the revocation, the reason(s) for the revocation, and a description of the prescriber's appeal rights concerning the revocation.''

++ New § 423.120(c)(6)(v)(B)(*2*) would state: ''The appeals of the prescriber's inclusion on the preclusion list and the prescriber's revocation shall be filed jointly by the prescriber and, as applicable, considered jointly by CMS under part 498 of this chapter.''

++ New § 423.120(c)(6)(v)(C)(*1*) would state: ''Except as provided in paragraph (c)(6)(v)(C)(*2*), a prescriber will only be included on the preclusion list after the expiration of either of the following:''.

++ New § 423.120(c)(6)(v)(C)(*1*)(*i*) would state: ''If the prescriber does not file a reconsideration request under § 498.5(n)(1) of this chapter, the prescriber will be added to the preclusion list upon the expiration of the 60-day period in which the prescriber may request a reconsideration; or''.

++ New § 423.120(c)(6)(v)(C)(*1*)(*ii*) would state: ''If the prescriber files a reconsideration request under § 498.5(n)(1) of this chapter, the prescriber will be added to the preclusion list effective on the date on which CMS, if applicable, denies the prescriber's reconsideration.

++ New § 423.120(c)(6)(v)(C)(*2*) would state: ''An OIG excluded prescriber is added to the preclusion list effective on the date of the exclusion.''

++ New § 423.120(c)(6)(vii)(A) would state: ''Except as provided in paragraphs (c)(6)(vii)(C) and (D) of this section, a prescriber who is revoked under § 424.535 of this chapter will be included on the preclusion list for the same length of time as the prescriber's reenrollment bar.''

++ New § 423.120(c)(6)(vii)(B) would state: ''Except as provided in paragraphs (c)(6)(vii)(C) and (D) of this section, a prescriber who is not enrolled in Medicare will be included on the preclusion list for the same length of time as the reenrollment bar that CMS could have imposed on the prescriber had the prescriber been enrolled and then revoked.''

++ Section 423.120(c)(6)(vii)(C) would state: ''Except as provided in paragraph (c)(6)(vii)(D) of this section, a prescriber, regardless of whether the prescriber is or was enrolled in Medicare, that is included on the preclusion list because of a felony conviction will remain on the preclusion list for a 10-year period, beginning on the date of the felony conviction, unless CMS determines that a shorter length of time is warranted. Factors that CMS considers in making such a determination are: (1) The severity of the offense; (2) when the offense occurred; and (3) any other information that CMS deems relevant to its determination.''

++ Section 423.120(c)(6)(vii)(D) would state: ''In cases where a prescriber is excluded by the OIG, the prescriber shall remain on the preclusion list until the expiration of the CMS-imposed preclusion list period or reinstatement by the OIG, whichever occurs later.

++ New paragraph (c)(6)(viii) would state: ''Payment denials under paragraph (c)(6) that are based upon the prescriber's inclusion on the preclusion list are not appealable by beneficiaries.''

• We propose to revise 42 CFR part 498 as follows:

++ New § 498.5(n)(1)(i) would state: ''Any individual or entity that is dissatisfied with an initial determination or revised initial determination that they are to be included on the preclusion list (as defined in § 422.2 or § 423.100 of this chapter) may request a reconsideration in accordance with § 498.22(a).''

++ New § 498.5(n)(1)(ii)(A) would state: ''If the individual's or entity's inclusion on the preclusion list is based on a Medicare revocation under § 424.535 of this chapter and the individual or entity receives contemporaneous notice of both actions, the individual or entity may request a joint reconsideration of both the preclusion list inclusion and the revocation in accordance with § 498.22(a).''

++ New § 498.5(n)(1)(ii)(B) would state: ''The individual or entity may not submit separate reconsideration requests under paragraph (n)(1)(ii)(A) of this section for inclusion on the preclusion list or a revocation if the individual or entity received contemporaneous notice of both actions.''

2. Medicare Advantage Risk Adjustment Data Validation Provisions (§§ 422.300, 422.310(e), and 422.311(a))

a. Background

Subpart G of the MA regulations at part 422 describes how payment is made to MA organizations. These payment principles are based on sections 1853, 1854, and 1858 of the Act. Subpart G also sets forth the requirements for making payments to MA organizations offering local and regional MA plans, including calculation of MA capitation rates.

Section 1853(a)(3) of the Act requires that we risk adjust our payments to MA organizations. Risk adjustment strengthens the Medicare program by ensuring that accurate payments are made to MA organizations based on the health status plus demographic characteristics of their enrolled beneficiaries and ensures that MA organizations are paid appropriately for their plan enrollees (that is, less for healthier enrollees expected to incur lower health care costs and more for less healthy enrollees expected to incur higher health care costs). Accurate payments to MA organizations also help ensure that providers are paid appropriately for the services they provide to MA beneficiaries. In general, the current risk adjustment methodology relies on enrollee diagnoses and encounters, as specified by the International Classification of Disease, currently the Tenth Revision Clinical Modification guidelines (ICD–10–CM), to prospectively adjust capitation payments for a given enrollee based on the health status of the enrollee. Diagnosis codes determine the risk scores, which in turn determine the risk-adjusted payments. As a result, MA organizations and providers must focus attention on complete, truthful, and accurate diagnosis reporting according to the official ICD–10–CM coding guidelines.

As the ICD–10–CM guidelines emphasize, ''accurate coding cannot be achieved'' without ''consistent, complete documentation in the medical record.'' Diagnoses submitted for payment by MA organizations must be supported by medical record documentation. This requirement has been in place since the beginning of the MA program. It has been explained in every edition of the Medicare Managed Care Manual, with which MA organizations agree to comply as a condition of their participation. (See the 2013 Medicare Managed Care Manual, § 40; 2004 Medicare Managed Care Manual, § 111.1, Ex. 30 & § 111.4; 2001 Medicare Managed Care Manual, § 110.4.) It has also been emphasized in numerous trainings provided to MA organizations and their subcontractors.

The diagnosis data submitted by MA organizations must conform to all relevant national standards. (See 42 CFR 422.310(d)(1).) As discussed earlier, the Clinical Modification of the International Classification of Disease, published by the federal government, is the chief national standard for diagnosis coding. It is the coding system on which MA risk adjustment is run. Medical record documentation is a core principle of the ICD–10–CM diagnosis coding system and was equally central to the Ninth Revision (ICD–9–CM), which preceded it. A federal court of appeals has recognized the requirement of medical record documentation for diagnosis codes submitted for payment by MA organizations. *United States ex rel. Swoben* v. *United Health Ins. Co.,* 848 F.3d 1161, 1168, 1176 (9th Cir. 2016). When MA organizations certify that their diagnosis codes are ''accurate'' and ''truthful'' to the ''best knowledge, information, and belief'' of the certifying individual, the existence of adequate medical record documentation is one important standard by which accuracy and truthfulness are measured (42 CFR 422.504(l)(1)). As we have previously explained, our ''risk adjustment methodology provides that a specific amount be paid if an enrollee has a particular condition'' (75 FR 19745). The medical record documentation requirement is ''designed to ensure that the enrollee in fact has th[e] condition'' for which an MA organization is requesting payment under the risk adjustment model (75 FR 19745).

The current risk adjustment model employed in adjusting MA plan payments is known as the CMS Hierarchical Condition Category (CMS–HCC) model. It functions by categorizing ICD–10–CM codes into disease groups called Hierarchical Condition Categories, or HCCs. Each HCC includes diagnosis codes that are related clinically and have similar cost implications. The CMS–HCC model is recalibrated approximately every 2 years to reflect newer treatment and coding patterns in Medicare FFS. This recalibration is made through the annual advance notice of methodological changes authorized by 42 U.S.C. 1395w–23(b)(2). Since 2007, when a demographic data-only payment method was completely phased-out for MA plans, 100 percent of payment has been risk-adjusted. The statute continues to provide us the authority to add to, modify, or substitute for risk adjustment factors if the changes will improve the determination of actuarial equivalence.

b. Risk Adjustment Data Validation Initiatives

MA enrollee HCCs are assigned based on data submitted to us by MA organizations via the Risk Adjustment Payment System (RAPS) and Encounter Data System (EDS). The HCCs contribute to an enrollee's risk score, which is used to adjust a base payment rate. Essentially, the higher the risk score for an enrollee, the higher the expected health care cost for the enrollee. The HCC data that MA organizations submit to CMS via the RAPS and EDS systems is self-reported by the MA organization and does not go through a validation review before being incorporated into a given beneficiary's risk-profile. Since there is an incentive for MA organizations to potentially over-report diagnoses so that they can increase their payment, the Department audits plan-submitted diagnosis data a few years later to ensure they are supported by medical record documentation.

Verifiable medical record documentation is key to accurate payment and successful data validation. We annually select MA organizations for risk adjustment data validation (RADV) audits.[23] RADV audits are intended to confirm the presence of risk adjustment conditions (that is, diagnoses that map to HCCs) as reported by MA organizations for their enrollees and confirmed via medical record documentation. RADV audits occur after the final risk adjustment data submission deadline for the MA contract year. The audits validate the HCC data submitted by MA organizations by reviewing hospital inpatient, hospital outpatient, and physician/practitioner provider medical records. The focus of this medical record review activity is on diagnoses related to the enrollee's HCC profile. Risk adjustment discrepancies are identified when the enrollee's HCCs used for payment (based upon MA organization-submitted data) differ from the HCCs assigned based on the medical record, pursuant to the RADV audit

[23] Any changes to the CMS–HCC payment model are published in the annual payment notice.

process. Risk adjustment discrepancies can be aggregated to determine an overall level of payment error. In turn, payment error for a sample of contract enrollees can be extrapolated to calculate a contract-level payment error estimate. Although we have the authority to extrapolate from a statistically valid sample to calculate a contract-level audit recovery, we have not yet done so.

From 1999 until 2003, our payment validation activity for the MA program had both an educational and audit focus and was intended to improve the accuracy of the risk adjustment data that was being submitted to CMS for payment. Payment adjustments were limited to enrollee-level adjustments for those enrollees sampled in the payment validation audit. At the time, only 10 percent of the MA payment amount was risk adjusted. As a result, payment recovery amounts for the small number of plans audited was very small. Since payment year 2004 was the first year for which MA payments were based on the current HCC risk adjustment model, we considered payment years 2004 through 2006 as pilot years for the purpose of RADV and no payment recovery activity occurred.

Payment recovery resumed for payment year 2007, when we audited 37 MA contracts and recouped $13.7 million. Payment adjustments were again limited to enrollee-level adjustments for those enrollees sampled in the payment validation audit. (Although we suggested that we would make contract-level payment adjustments for the payment year 2007 audits, we did not ultimately do so.) In the course of that audit process, as in previous years, we reviewed medical record documentation provided by each audited MA organization to substantiate conditions reported by the organization for beneficiaries in each audit sample. After CMS' findings were reported to each MA organization, any organization that disagreed with CMS' determinations could challenge them through a three-stage administrative process established by regulation in 2010. (See 42 CFR 422.311). This dispute and appeals process is currently ongoing.

No payment validation audits were conducted for payment years 2008, 2009, or 2010. In those years, we were considering the development of a methodology for calculating payment adjustments based on statistical RADV MA contract-level payment error audit findings. The development of contract-level RADV audits would enable us to make contract-level payment adjustments rather than simply adjusting payments for specific enrollees from an audit sample, as we had done previously.

On December 20, 2010, we proposed a methodology on the CMS website for selecting a statistically-valid sample of enrollees from each audited MA contract and extrapolating from the results of that sample audit to calculate a contract-level payment adjustment. We invited public comment on this proposed methodology, and received more than 500 comments, which we carefully reviewed. On February 24, 2012, we published what we described as the final methodology for RADV contract-level payment error calculation.[24] That methodology described sampling techniques and the statistical calculation to be used to extrapolate from the sample selected. In brief, up to 201 enrollees from each audited MA contract would be selected according to certain criteria, including their continuous enrollment in the contract for the entire data collection year and January of the payment year; their lack of end-stage renal disease (ESRD) status and hospice status for that entire period; their enrollment in Medicare Part B coverage for the entire data collection year; and their submission of at least one diagnosis during the data collection year leading to at least one CMS–HCC assignment in the payment year. The RADV-eligible enrollees would be ranked by risk score and then divided into three equal strata. An equal number of enrollees would then be randomly selected from each stratum (67 enrollees per stratum in the case of an audit of 201 enrollees). After medical records were reviewed, payment errors would be calculated for each selected enrollee based on the number of months the person was enrolled in the selected MA contract (and was not in ESRD or hospice status) during the payment year. A payment error rate for each stratum would be calculated, and then an overall payment error rate for the audited contract, computed at a ninety-nine percent confidence interval. We stated that this methodology would be applied to the next round of RADV audits, which would be conducted on payment year 2011. Audits for payment years 2011, 2012, and 2013 have been conducted according to this methodology, at a total cost of approximately $150 million to the agency, but have not yet been finalized. These audits are in addition to RADV and related MA audits conducted by the Office of Inspector General, which are conducted pursuant to OIG's independent authorities at sections 2(1) and 4(a)(1) of the Inspector General Act.

We also stated in 2012 that, after using this methodology to calculate a preliminary payment recovery amount, we would apply a FFS Adjuster as an offset before finalizing the audit recovery. The FFS Adjuster was intended to account for any effect of erroneous diagnosis codes in the data from Medicare Parts A and B (often referred to as ''Fee-For-Service'' Medicare) that are used to calibrate the MA risk adjustment model. We stated that the FFS Adjuster would calculate a permissible level of payment error (for example, a percentage of the total payments made on an MA contract in a given year) and limit RADV audit recovery to payment errors above that level. The FFS Adjuster was never intended to set a permissible rate for the submission of erroneous diagnosis codes. We stated that the FFS Adjuster would be calculated based on a RADV-like review of records submitted to support the Medicare Part A and B diagnosis codes. That review is now complete, and will be discussed later.

c. Discussion of Proposals

(1) Extrapolation

The Secretary intends to recover overpayments based on extrapolated audit findings through the use of statistically valid random sampling techniques. Although we described our February 2012 publication as the final methodology to be used to calculate contract-level RADV audit recoveries for payment year 2011, it has never been implemented. As we stated earlier, audits for payment years 2011, 2012, and 2013 have been conducted according to this methodology, but contract-level recoveries have not yet been sought. We are now providing additional notice and again welcoming public input on the agency's methodology for calculating a contract-level payment error in RADV audits, including the sample sizes used in these contract-level audits. CMS is not required to set forth the methodology for calculating an extrapolated payment error through regulatory provisions (it does not do so in Parts A and B, where Medicare Administrative Contractors (MACs) may use any statistically valid sampling and extrapolation methodology they determine to be appropriate), however, in the interest of transparency, we are updating

[24] Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits, *available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program-parts-c-and-d/Other-Content-Types/RADV-Docs/RADV-Methodology.pdf.*

stakeholders on our plans to use various sampling and extrapolation methodologies in RADV audits, as CMS deems appropriate.[25] All audits will be based on statistically valid sampling and extrapolation methodologies.

In addition to the contract-level methodology described earlier, we have identified other potential methodologies for sampling and extrapolation, which would calculate improper payments made on the audited MA contract for a particular sub-cohort or sub-cohorts in a given payment year, and the agency may also use such a methodology to calculate improper payments made to the audited MA contract. For example, a sub-cohort could be the enrollees for whom a particular HCC or one of a related set of HCCs (such as the three diabetes HCCs) was reported. After choosing an MA contract and a sub-cohort or sub-cohorts to audit, we would select a statistically significant sample of enrollees for the sub-cohort or sub-cohorts. After reviewing the medical records of those enrollees, we would use statistical extrapolation to calculate and recoup the improper payments made to the audited MA contract for covering enrollees for the sub-cohort or sub-cohorts in that payment year. We would use the same statistical calculation for this sub-cohort-level extrapolation as we do for the contract-level extrapolation (although we welcome comment as to whether to stratify the sample population for the sub-cohort audits, as we currently anticipate doing for the contract-level audits).

We believe that, because any sub-cohort is necessarily a subset of the enrollees covered through a particular MA contract, we could often use a much smaller sample size to calculate a statistically significant extrapolated recovery for a sub-cohort than would be required to calculate a contract-level recovery (up to 201 enrollees, according to our anticipated contract-level methodology). This smaller sample size would allow us to spread our audit resources across a wider range of MA contracts, while still generating statistically significant recoveries. This sub-cohort-based audit methodology would allow us to focus on cohorts of enrollees that appear to raise programmatic concerns.

We invite comment on both the contract-level audit methodology published in February 2012, and our proposal for an extrapolated audit methodology based on sub-cohorts of enrollees. We also seek comment on whether there are particular situations in which one methodology may be preferable to the other, and whether the agency should revise the contract-level audits that have been conducted but not finalized for payment years 2011, 2012, and 2013. Neither proposed methodology is meant to displace our longstanding authority to audit the medical records of particular enrollees who we believe may be associated with improper payments or to use any statistically valid audit methodology.[26]

If we finalize one or more sampling and extrapolation methodologies through this rulemaking, we would make any future changes to that methodology (or those methodologies) through the Health Plan Management System.

We are also considering whether to explicitly expand the MA organizations' RADV appeal rights, particularly in light of the upcoming auditing and recoveries in the MA program. One option would be to permit appeal of the RADV payment error calculation methodology used in a RADV audit similar to practices in the Part A and Part B space of Medicare FFS. We invite comments on this matter.

(2) Application to Payment Year 2011 and Subsequent Years

We intend to apply the finalized RADV payment error methodology or methodologies to payment year 2011, and all subsequent years. (However, we do not expect to use a sub-cohort-based methodology, if finalized, for any payment year before 2014). Section 1871(e)(1)(A) of the Act authorizes retroactive application of rules where ''(i) such retroactive application is necessary to comply with statutory requirements; or (ii) failure to apply the change would be contrary to the public interest.'' We are considering whether application of the finalized methodology or methodologies to payment year 2011, and all subsequent years, would require the exercise of this statutory authority to engage in retroactive rulemaking. We invite comment on the subject.

In any case, we believe that failure to apply the finalized RADV payment error methodology or methodologies to those payment years would be contrary to the public interest. The public has a substantial interest in the recoupment of millions of dollars of public money improperly paid to private insurers. The public also has a significant interest in providing incentives for those insurers to claim only proper payments in the future, which would be promoted by the recoupment of funds improperly paid in the past. Given the amount of improper payments identified under the MA program (estimated to be $14.35 billion in FY 2017,[27] the $650 million in recovered improper payments represents, if this policy was finalized, 3 years improper payment for 30 plans), the interest in determining an accurate recovery amount for each audited MA plan, and the importance of protecting the overall integrity of the program, we believe that it is in the public interest for CMS to apply the RADV payment error methodology or methodologies adopted through this rulemaking to payment year 2011 and all subsequent years. In applying this methodology (or these methodologies) to those payment years, CMS would be acting in compliance with the IPERIA statute [28] as

[25] The Office of the Inspector General, which is required by law to conduct audits and follow generally accepted government auditing standards, does not seek comment on its methodology for risk adjustment audit work that may lead to overpayment recoveries from MA organizations.

[26] We may begin to conduct RADV audits for payment years 2014 and 2015 before this proposal is finalized, pursuant to our longstanding authority to review the medical records of any MA enrollee and recoup any improper payments identified. Although we would design these audits so that the individuals selected would form a statistically significant sample that would support an extrapolated recovery, we would not seek to recover on an extrapolated basis until the rule is final. At the very least, these audits would support enrollee-level recoveries.

[27] CMS has historically reported high levels of payment error in the Part C program. The Part C error rate has ranged between 11 percent and 9 percent between fiscal years (FY) 2011 and 2014, respectively. In FY 2017, the reported Part C error rate was 8.31 percent or $14.35 billion.

[28] Improper Payments Elimination and Recovery Improvement Act of 2012 (IPERIA, Pub. L. 112–248). The RADV program is a corrective audit activity developed by CMS to address provisions included in the IPIA of 2002, as amended by the IPERA of 2010, and further amended by IPERIA. These statutes require that government agencies annually estimate and report improper payments. RADV audits were initiated because Part C payment error was out of compliance with IPIA. The IPERIA requires the Office of Management and Budget (OMB) to annually identify agencies for greater levels of oversight and review, and with that agency ''establish annual targets and semi-annual or quarterly actions for reducing improper payments associated with each high-priority program.'' In November 2009, Executive Order (E.O.) 13520 was signed in an effort to reduce improper payments by increasing transparency in government and holding agencies accountable for reducing improper payments. In March 2010, OMB issued guidance for agencies regarding the implementation of E.O. 13520 entitled Part III to OMB Circular A–123, Appendix C (Appendix C). Appendix C outlines the responsibilities of agencies, determines the programs subject to E.O. 13520, defines supplemental measures and targets for high priority programs, and establishes reporting requirements under E.O. 13520 and procedures to identify entities with outstanding payments. One of those remedies is payment recapture audits, a requirement that any program that expends at least $1 million must implement payment recapture audits. A recovery audit, or payment recapture audit, is a review process designed to identify erroneous payments. Additionally, it is a corrective

Continued

well as its own fiduciary responsibility to recover funds due and owing to the Medicare Trust Funds. We note also that our February 2012 publication put MA organizations on notice that CMS expected to calculate a contract-level payment error for payment year 2011 and beyond by extrapolating from its review of a statistically valid sample of enrollees, and that (as explained earlier) MA organizations have never been entitled to receive or retain payments associated with HCCs that cannot be validated by medical records. Application of the finalized RADV payment error methodology or methodologies to payment year 2011 and all subsequent years therefore would not upset any settled interest.

If the finalized contract-level audit methodology differs from the one we published in February 2012, we will also consider whether to apply the new contract-level payment error methodology to payment years 2011, 2012, and 2013, or to only apply it to payment year 2014 and subsequent years, and to finalize the audits for those earlier payment years according to the methodology published in February 2012. We invite comment on this subject, as well. In any event, and however audits for prior years are ultimately handled, we believe that it is vitally important for the health of the MA program to have extrapolated recoveries available for future audit years.

(3) Implementation

This proposal would announce CMS' intention to recover improper payments based on extrapolation of payment error from RADV audit samples to MA organization specified populations. CMS would calculate and recover improper payments based on extrapolation methodologies. MA organizations would be required to remit extrapolated recovery amounts from audit findings as calculated by CMS through its payment system, Medicare Advantage and Prescription Drug system (MARx). MARx is the CMS system that makes monthly payments and payment adjustments to the MA organizations and Part D sponsors. Overpayment recoveries of all types are considered payment adjustments which are done as offsets to the plans' monthly payments. RADV recovery amounts are included in this category. In the month the plan has been notified that the recovery amount will be offset, the MARx system makes an offset to the plans monthly payment equal to the amount of the recovery amount. In the event the recovery amount exceeds the payment in 1 month, the recovery will be spread across adjustments for multiple months until the full amount is recovered. CMS may likewise require MA organizations to remit such recovery amounts based upon audit findings by OIG.

(4) Recoupment of Improper Payments in Part C

Improper payments identified by CMS outside of the RADV audit process or self-identified by the MA organization that are not returned in accordance with §§ 422.330, and are identified and/or estimated through extrapolation or other estimation methodologies as a result of CMS audits will be recovered following CMS audit processes including payment offset. We propose that MA organizations be required to remit funds that CMS calculates as improper payments through the extrapolated RADV audit findings in accordance with §§ 422.310(e). RADV audit results can be appealed by MA organizations using the regulatory administrative appeals process outlined in § 422.311.

(5) FFS Adjuster

After our 2012 RADV publication, we conducted an extensive study regarding the presence and impact of diagnosis error in FFS claims data. Our study suggests that errors in FFS claims data do not have any systematic effect on the risk scores calculated by the CMS–HCC risk adjustment model, and therefore do not have any systematic effect on the payments made to MA organizations.[29]

The study began by auditing 8,630 outpatient claims paid through Medicare Part B in a given year. We reviewed the medical records associated with each claim (a small subset of the medical records associated with each beneficiary) to determine whether the diagnosis associated with the claim was supported by medical record documentation. A discrepancy rate for each CMS–HCC was then calculated. For example, the data set contained 484 claims submitted with a diagnosis of chronic obstructive pulmonary disease, which is CMS–HCC 108. Of those diagnoses, 388 were supported by medical record documentation, and 96 were not, for a discrepancy rate of 19.8 percent. To account for the fact that the data set contained extremely small samples of many CMS–HCCs—for example, one diagnosis of extensive third degree burns and two diagnoses of severe head injury—we calculated a high, low, and baseline discrepancy rate. Each CMS–HCC was assigned one of these three mean discrepancy rates depending on its relationship to the bassline discrepancy rate: CMS–HCCs with a discrepancy rate significantly higher than the baseline were assigned to the high category, and those with a discrepancy rate significantly lower than the baseline were assigned to the low category. All other CMS–HCCs were assigned the baseline discrepancy rate. These rates were 46.2 percent, 33.8 percent, and 20.9 percent.

In a given year, multiple claims are submitted for Medicare Part B services received by a given beneficiary and associated with a given diagnosis. For example, an average beneficiary with metastatic cancer or acute leukemia, which is CMS–HCC 7, has seven claims associated with that diagnosis. Because we were interested in determining whether a given beneficiary had a documented diagnosis in a given year, and not whether any particular claim was associated with medical record documentation, we used the claim-level discrepancy rates described above to calculate beneficiary-level discrepancy rates.[30]

After calculating this beneficiary-level discrepancy rate for each HCC, we ran fifty simulations in which we removed diagnoses from a data set of more than 1.4 million Medicare Part A and B beneficiaries at the beneficiary-level discrepancy rate.[31] After removing diagnoses at the indicated rates, we used each simulated ''corrected'' data set to recalibrate the CMS–HCC risk adjustment model, applied the recalibrated risk coefficients to a data set of MA beneficiaries, and compared their original risk scores to the risk

control activity designed to identify and recapture erroneous payments, and, as such, is a management function and responsibility.

[29] We are aware of the district court's recent ruling in *United HealthCare Insurance Co.* v. *Azar,* No. 16-cv-157 (D.D.C. September 7, 2018), and the government is reviewing that decision and considering its response. In any event, that ruling was made on the basis of the administrative record before the court, which did not include the results of our study.

[30] For example, metastatic cancer or acute leukemia was assigned the baseline discrepancy rate of 33.8%. We therefore reasoned that each of the seven claims associated with the average beneficiary for whom such a diagnosis was reported had a 66.2% chance of being supported by medical record documentation, and only one instance of medical record support was necessary to make the diagnosis valid for that year. If each beneficiary with such a reported diagnosis has 7 claims associated with that diagnosis, and each claim has a 66.2% chance of being supported by medical record documentation, then 99.95% of all beneficiaries will have at least one instance of medical record support, and only 0.05% of beneficiaries will lack any medical record documentation of their reported diagnosis.

[31] For metastatic cancer and acute leukemia, 1 in 2,000 diagnoses was removed (corresponding to an error rate of 0.05%).

scores calculated with the recalibrated model. We found that the difference between the risk scores was very small, and that the recalibrated risk scores tended to be slightly lower than the original risk scores. Therefore, we concluded that diagnosis error in FFS claims data does not lead to systematic payment error in the MA program.

An executive summary of the findings and a technical appendix describing the data and methodology can be found at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Resources.html.* Because it appears that diagnosis error in FFS claims data does not lead to systematic payment error in the MA program, we propose not to include an FFS Adjuster in any final RADV payment error methodology.

Moreover, even if we had found that diagnosis error in FFS claims data led to systematic payment error in the MA program, we no longer believe that a RADV-specific payment adjustment would be appropriate. RADV audits are used to recover payments based on diagnoses that are not supported by medical record documentation, which thus should not have been reported to CMS. If a payment has been made to an MA organization based on a diagnosis code that is not supported by medical record documentation, that entire payment is in error and should be recovered in full, because the payment standard has not been met, and the MA organization is not entitled to any payment for that diagnosis. RADV audits do not address issues with the accuracy of payments based on diagnosis codes that are supported by medical record documentation. Consequently, an adjustment to RADV recoveries to remedy payment accuracy concerns is inappropriate. For this reason, we believe that it would not be appropriate to correct any systematic payment error in the MA program through a payment adjustment that was only applied to audited contracts. Doing so would introduce inequities between audited and unaudited plans, by only correcting the payments made to audited plans.

Because our study suggests that diagnosis error in FFS claims data does not lead to systematic payment error in the MA program and because we believe it would be inequitable to correct any systematic errors in the payments made to audited plans only, we would not include an FFS Adjuster in any RADV extrapolated audit methodology. We welcome public comments on this study.

d. Proposed Changes

In this section, we discuss the proposed changes to the regulation in Parts 422 and 423 governing the MA Program. We are proposing to apply extrapolation to plan year audits for payment year 2011 forward.

The following is a summary of the proposed changes included in this proposed revision:

We propose to revise § 422.300 to include ''collection of improper payments.''

We propose to amend § 422.310(e) Validation of risk adjustment data, to apply extrapolation to plan year audits for payment year 2011 forward.

We propose to amend § 422.310(e) Validation of risk adjustment data, by adding a requirement to set forth the provision for MA organizations to remit improper payments based on RADV audits and established in accordance with stated methodology, in a manner specified by CMS.

We propose to amend § 422.311, the RADV audit dispute and appeal process section, by adding language to clarify that recovery of improper payments from MA organizations will be conducted according to the Secretary's payment error extrapolation and recovery methodologies and that CMS will apply extrapolation to plan year audits for payment year 2011 forward.

D. Implementing Other Changes

1. Clarification Regarding Accreditation for Quality Improvement Programs

Section 1852(e) of the Act requires each MA organization to have an ongoing quality improvement program to improve the quality of care provided to its enrollees and establishes the requirements for the quality improvement programs. Section 1852(e)(4) of the Act requires the Secretary to deem that an MA Organization has met all of the requirements for any one out of the six program areas listed in section 1852(e)(4)(B) of the Act if the MA Organization is accredited in that area by an accrediting organization that has been approved by CMS and that uses the same (or stricter) standards than CMS uses to evaluate compliance with the applicable requirements. Section 1852(e)(4)(B)(i) of the Act references the quality improvement programs in section 1852(e) of the Act. Thus, an MA Organization could be deemed to meet CMS' requirements related to quality improvement programs by a CMS-approved accrediting organization.

Section 722(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the MMA) revised the quality improvement program requirements in the Act. Section 1852(e) of the Act was revised by adding a new clause ''(2) Chronic Care Improvement Programs'' and renumbering the existing clauses accordingly (that is, existing clause ''(2) Data'' became ''(3) Data''). Section 722(a) of the MMA also revised section 1852(e)(4)(B)(i) of the Act. Prior to the MMA, section 1852(e)(4)(B)(i) of the Act indicated that the requirements in clauses (e)(1) (general requirements for quality improvement programs) and (e)(2) (the collection, analysis, and reporting of data related to quality improvement programs) could be deemed. Consistent with the changes made to section 1852(e) of the Act described earlier, section 722(a) of the MMA amended section 1852(e)(4)(B)(i) of the Act to provide, ''(i) Paragraphs (1) through (3) of this subsection (relating to quality improvement programs).'' However, the printed and online versions of section 1852(e)(4)(B)(i) of the Act continue to cross-reference clauses (e)(1) and (e)(2) erroneously. Therefore, we are clarifying in this proposed rule that the requirements in section 1852(e)(3) of the Act and the subsections of § 422.152 related to section 1852(e)(3) of the Act may be deemed.

2. Delete the Reference to Quality Improvement Projects in § 422.156(b)(1)

Section 1852(e) of the Act requires each MAO to have an ongoing Quality Improvement (QI) Program for the purpose of improving the quality of care provided to its enrollees. Our regulations at § 422.152 outline the QI Program requirements MA Organizations. Section 422.152(a)(3) requires each MA Organization to conduct quality improvement projects (QIPs) for its enrollees, and § 422.152(d) establishes the requirements for the QIPs. Effective January 1, 2019, CMS eliminated the requirements for QIPs in §§ 422.152(a)(3) and 422.152(d) in the April 2018 final rule (83 FR 16440). However, the reference to QIPs was not deleted in § 422.156(b)(1), which says QIPs are exempt from the process for deeming compliance based on accreditation. Therefore, we are proposing a technical correction in this rule that would delete the phrase ''the quality improvement projects (QIPs) and'' from § 422.156(b)(1).

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of

information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection 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.

In this proposed rule, we are soliciting public comment on each of these issues for the following sections of this rule that contain proposed ''collection of information'' requirements as defined under 5 CFR 1320.3 of the PRA's implementing regulations.

A. Wage Data

To derive average costs for the private sector, we used data from the U.S. Bureau of Labor Statistics' (BLS's) May 2017 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). In this regard, Table 2 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 2: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Overhead ($/hr)	Adjusted Hourly Wage ($/hr)
Business Operation Specialist	13-1000	34.54	34.54	69.08
Lawyer	23-1011	68.22	68.22	136.44
Programmer	15-1311	40.95	40.95	81.90

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. We believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

B. Proposed Information Collection Requirements (ICRs)

1. ICRs Regarding the Requirements for Medicare Advantage Plans Offering Additional Telehealth Benefits (§§ 422.100, 422.135, 422.252, 422.254, and 422.264)

Proposed revisions to the Evidence of Coverage (EOC) model to take into account the new type of benefit will be submitted to OMB for approval under control number 0938–1051 (CMS–10260).

As described in section II.A.1. of this proposed rule, section 50323 of the Bipartisan Budget Act of 2018 allows MA plans to provide ''additional telehealth benefits'' to enrollees starting in plan year 2020 and treat them as basic benefits for purposes of bid submission and payment by CMS. In this rule, we propose to codify requirements at § 422.135, which would authorize and set standards for MA plans to offer additional telehealth benefits.

More specifically, MA plans would be required to advise enrollees that they may receive the specified Part B service(s) either through an in-person visit or through electronic exchange. This notification would appear in the EOC document, which is already required and provided in model form by CMS to MA plans. There is a one-time cost for CMS to formulate the required template notification language in our EOC model for all plans to adopt without edit. Since CMS's burden to revise the model is outside the scope of the PRA, the federal cost estimate is scored in section IV.C.1. of this proposed rule. The revised template, however, is subject to the PRA and will be submitted to OMB for their review and approval.

MA plans would also be required to use their provider directory to identify any providers offering services for additional telehealth benefits and in-person visits or offering services exclusively for additional telehealth benefits. Like the EOC, the provider directory is already required and provided in model form by CMS, with MA plans obligated to and responsible for populating the document with the relevant information about the providers in the MA plan's contracted network. It is difficult to assess the additional burden associated with this requirement because the provider directory model already requires plans whose providers may have restrictions on access to include a notation next to the provider's listing indicating such restrictions. We are unsure what, if any, additional burden may be associated with this new data field and we seek information that may inform the burden.

Finally, MA plans would be required to make information about coverage of additional telehealth benefits available to CMS upon request. We do not anticipate requesting this information from more than 9 MA plans in a given year because historically we have not received a large number of complaints about coverage of benefits that might warrant us requesting information from many plans. However, we would like to reserve the right to ask for this information if necessary. Since we estimate fewer than ten respondents, the information collection requirement is exempt (5 CFR 1320.3(c)) from the requirements of the PRA.

2. ICRs Regarding Integration Requirements for Dual Eligible Special Needs Plans (§§ 422.2, 422.60, 422.102, 422.107, 422.111, and 422.752)

The following proposed requirements and burden will be submitted to OMB for approval under control number 0938–0753 (CMS–R–267).

As described in section II.A.2.a. of this proposed rule, we propose to establish new requirements in accordance with amendments to section 1859(f)(8) of the Act (made by section 50311(b) of the Bipartisan Budget Act of 2018), which stipulates that all dual eligible special needs plans (D–SNPs) meet certain new minimum criteria for Medicare and Medicaid integration for 2021 and subsequent years. We also propose to codify the various forms of integrated care provided by D–SNPs that have evolved since their establishment nearly 15 years ago.

In § 422.107(d), we propose that any D–SNP that is not a fully integrated dual eligible special needs plan (FIDE SNP) or a highly integrated dual eligible special needs plan (HIDE SNP), as defined in proposed § 422.2, would be subject to an additional contracting requirement. Under the additional contracting requirement, the D–SNP would notify the state Medicaid agency and/or individuals or entities designated by the state Medicaid agency of hospital and skilled nursing facility (SNF) admissions for at least one group of high-risk full-benefit dual eligible individuals, as determined by the state Medicaid agency.

We also propose modifications to existing requirements for the contract between states and D–SNPs at § 422.107(b) and (c). These modifications would include requirements that D–SNPs: Document their responsibility to provide, as applicable, or coordinate the delivery of Medicaid benefits; specify the categories and criteria for dual eligible individuals to be enrolled in the plan; and specify the Medicaid benefits covered by the MA organization offering the D–SNP or under a risk contract with a Medicaid managed care organization offered by the D–SNP's parent organization or another entity that is owned and controlled by its parent organization.

The primary burden arising from the proposals would consist of the following:

- Burden to the state to—

++ Execute D–SNP contract modifications; and

++ Set the terms of the notification, including its method, timing, and scope, and for some states, receive a notification from D–SNPs about enrollees' hospital and SNF admissions.

- Burden to the D–SNP to—

++ Execute a contract modification with the state Medicaid agency;

++ Notify the state Medicaid agency or its designee(s) about enrollees' hospital and SNF admissions.

a. Burden to States

(1) Contract Modifications With D–SNPs (§ 422.107)

For the initial year, we expect it would take 24 hours at $136.44/hr for a lawyer to update the state Medicaid agency's contract with every D–SNP in its market. Since half of the cost would be offset by federal financial participation for Medicaid administrative activities, we have adjusted our estimates for state agencies by 50 percent. Given the market penetration of D–SNPs in certain states relative to others, we recognize that this estimate reflects an average cost across all states and territories with D–SNPs. We expect that the state Medicaid agency would establish a uniform requirement for all D–SNPs operating in their market. As of June 2018, there were 42 states, plus the District of Columbia and one territory (Puerto Rico), in which D–SNPs were available to MA enrollees. In aggregate, we estimate a one-time first year burden of 1,056 hours (44 respondents * 24 hr/response) at a cost of $72,040 (1,056 hr * $136.44/hr * 0.50).

While we recognize that, over time, states could modify this contract term, for example, by expanding the population of full-benefit dual eligible individuals to whom this notification applies, we do not believe that such a contract change would have a material impact on time and effort and, therefore, would already be accounted for in the burden estimate for the overall contract that the state Medicaid agency has with each D–SNP.

Given the lack of material impact and the uncertainty involved in estimating state behavior, we are estimating a minimum of zero burden in subsequent years on plans. The maximum burden would be the estimated first year cost. However, we believe the maximum estimate is unlikely to be accurate since we expect any changes to contracting requirements to be iterative compared to the first year update. We solicit public comment on our assumptions and whether there are reasonable ways of modeling state behavior.

(2) Notification (§ 422.107(d))

To address differences among the states in available infrastructure, population sizes, and mix of enrollees, this rule proposes broad flexibility identifying the groups for which the state Medicaid agency wishes to be notified and how the notification should take place. Flexibilities include: (1) Consideration of certain groups who experience hospital and SNF admissions; (2) protocols and timeframes for the notification; (3) data sharing and automated or manual notifications; and (4) use of a stratified approach over several years starting at a small scale and increasing to a larger scale. We would also allow states to determine whether to receive notifications directly from D–SNPs or to require that D–SNPs notify a state designee such as a Medicaid managed care organization, section 1915(c) waiver case management entity, area agency on aging, or other organization.

Some states, using a rich infrastructure and a well-developed automated system, may fulfill this requirement with minimal burden, while states with less developed or no infrastructure or automated systems may incur greater burden. Furthermore, the burden, especially to those states starting on a small scale, may differ significantly from year to year. Because of the flexibilities provided in this proposed rule, we expect states to choose strategies that are within their budget and best fit their existing or already-planned capabilities. We would expect any state choosing to receive notification itself of such admissions to claim federal financial participation under Medicaid for that administrative activity.

As of June 2018, there were 42 states, plus the District of Columbia and one territory (Puerto Rico), in which D–SNPs were available to MA enrollees. We estimate that there are nine states and territories with D–SNPs that all are expected to qualify as either FIDE SNPs or HIDE SNPs—Arizona, Florida, Hawaii, Idaho, Massachusetts, Minnesota, New Jersey, New Mexico, and Puerto Rico. We do not expect these states to establish a notification system under this proposal. We estimate that nine additional states that primarily use managed care for long-term services and supports (LTSS) (Michigan, North Carolina, New York, Ohio, Oregon, Pennsylvania, Tennessee, Texas, and Virginia) would delegate receipt of this information to their Medicaid managed care organizations. We further estimate that approximately half of the remaining 26 states—that is, 13 states—would build an automated system for receiving notification of hospital and SNF admissions consistent with this proposed rule.

We estimate that, on average, this work could be accomplished in a month with one programmer and one business analyst to define requirements. Accordingly, we estimate a one-time burden of 2,080 hours (13 states * 40 hr per week * 4 weeks) per worker. Since half of the cost would be offset by 50 percent federal financial participation for Medicaid administrative activities, we estimate a cost of $85,176 (2,080 hr * $81.90/hr * 0.50) for a programmer and a cost of $71,843 (2,080 hr * $69.08/hr * 0.50) for a business analyst. In aggregate, we estimate a burden of 4,160 hours (2,080 hr for a programmer + 2,080 hr for a business analyst) at a cost of $157,019 ($85,176 for a programmer + $71,843 for a business analyst) for the update.

Because of the possible wide variability in states' approaches in implementing this requirement, we solicit comment on and any other suggestions for modeling state

approaches and costs related to this provision. In addition, we believe that we have no reasonable way of estimating or illustrating burden in later years. The expected behavior among states is unknown relative to how often they will modify their notification mechanisms. Given the uncertainty involved in estimating state behavior, we are estimating a minimum of zero burden in future years on plans. The maximum burden would be the estimated first-year cost. However, we believe the maximum estimate is unlikely to be accurate since it would involve developing an automated notification system from the beginning rather than modifying an existing system. We solicit public comment on our assumptions.

b. Burden on Plans

(1) Contract Modifications With State Medicaid Agencies (§ 422.107)

For the initial year, we expect it would take 8 hours at $136.44/hr for a lawyer to update their plan's contract with the state Medicaid agency. Since states are identifying the high-risk populations for which they wish to be notified, it is reasonable to project that every D–SNP contract would negotiate one contract modification with the state Medicaid agency. There are 190 D–SNP contracts as of June 2018, of which 37 contracts, or 12.7 percent (about one-eighth), are FIDE SNPs.[32] We do not have a precise count of D–SNPs that will likely meet the proposed definition of a HIDE SNP. We assume another 12.7 percent of the 190 D–SNP contracts would be HIDE SNP contracts. Since the notification requirements are only applicable to D–SNPs that are not FIDE SNPs or HIDE SNPs, we expect that the number of contracts needing modification is 190 D–SNP contracts, less 37 FIDE SNP contracts, less 37 HIDE SNP contracts, or 116 D–SNP contracts. In aggregate, we estimate a one-time first year burden of 928 hours (116 D–SNPs * 8 hr) at a cost of $126,616 (928 hr * $136.44/hr).

We believe that we have no reasonable way of estimating or illustrating burden in later years. The expected behavior among states is unknown relative to how often they will modify their contracts with D–SNPs on this particular matter. For example, state Medicaid agencies may remain satisfied with the initial year selection of high-risk groups and see no reason to modify their contracts in later years. In contrast, other state Medicaid agencies may seek to expand the notification requirement to encompass additional groups of high-risk dually eligible individuals and may therefore modify their contracts on this basis.

Given the uncertainty involved in estimating state behavior, we are estimating a minimum of zero burden in subsequent years on plans. The maximum burden would be the first year costs. However, we believe this estimate is unlikely to be accurate given our expectation that contractual changes after the first year would be iterative at most. We solicit public comment on our assumptions and whether there are reasonable ways of modeling state behavior.

(2) Notifications to State Medicaid Agencies or Their Designees (§ 422.107(d))

We have noted previously the broad flexibility in notification options for states. We also note that MA organizations are already required to have systems that are sufficient to organize, implement, control, and evaluate financial and marketing activities, the furnishing of services, the quality improvement program, and the administrative and management aspects of the organization (§ 422.503(b)(4)(ii)). Independent of the state Medicaid agency's selection of high-risk populations, protocols, and notification schedules, an MA organization's most likely method of sharing this notification would be through the use of an automated system that could identify enrollees with criteria stipulated by the states and issue electronic alerts to specified entities. We do not believe that this work is very complex. Therefore, we estimate it could be accomplished in a month with one programmer and one business analyst to define requirements. The burden would be at the contract, not the plan, level and, as noted in section II.A.2.a. of this proposed rule, we estimate 116 affected D–SNP contracts. Accordingly, we estimate a first year burden of 18,560 hours (116 contracts * 40 hr * 4 weeks) per worker. The cost for programming would be $1,520,064 (18,560 hr * $81.90/hr) for a programmer and $1,282,125 (18,560 hr * $69.08/hr) for a business analyst. In aggregate, we estimate a burden of 37,120 hours (18,560 hr for a programmer + 18,560 hr for a business analyst) at a cost of $2,802,189 ($1,520,064 + $1,282,125).

Table 3 summarizes the burden of this provision.

TABLE 3: INDIVIDUAL AND AGGREGATE BURDEN OF PROPOSED D-SNP INTEGRATION REQUIREMENTS

Item	Number of Respondents	Hours per Respondent	Total Hours	Cost per Hour	Aggregate Total Cost (in $), First Year (Adjusted)	Aggregate Cost, Years 2 and 3
Initial update by state Medicaid agency of its contracts with D-SNPs	44 (States)	24	1,056	136.44	72,040	0
Initial establishment of system for notification of hospital and SNF admissions by state Medicaid agency	13	160	2,080	81.90	85,176	0
	13	160	2,080	69.08	71,843	0
Subtotal (State Burden)	*44*	*344*	*5,216*	*varies*	*229,059*	*0*
Initial update by D-SNPs of their contracts with the state Medicaid agency	116 (D-SNPs)	8	928	136.44	126,616	0
Initial notification of hospital and SNF admissions by D-SNPs to state Medicaid agency	116	160	18,560	81.90	1,520,064	0
	116	160	18,560	69.08	1,282,125	0
Subtotal (D-SNP Burden))	*116*	*328*	*38,048*	*varies*	*2,928,805*	*0*
TOTAL	160	Varies	43,264	Varies	3,157,864	0

[32] Centers for Medicare & Medicaid Services (2018, June). *SNP Comprehensive Report.* Retrieved from *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data.html.*

As indicated earlier, depending on each state's capacity, this initial year burden may suffice for several years or may change annually if states expand and change their criteria annually. Consequently, we are only estimating the initial year burden. The second and third year burden could therefore range between $0 and the full $3.1 million cost estimated for the first year. We are estimating, for years 2 and 3, a minimum of zero burden (the lower end of the range) because it is our understanding that most states and plans would not incur programming or contract related burden in years 2 and 3. We acknowledge that some states and plans may incur such burden. However, we have no reliable way to estimate the burden currently. We seek public input to help us confirm whether our zero burden estimate for years 2 and 3 is reasonable.

3. ICRs Regarding Unified Grievance and Appeals Procedures for Dual Eligible Special Needs Plans and Medicaid Managed Care Plans at the Plan Level (§§ 422.560 Through 422.562, 422.566, 422.629 Through 422.634, 438.210, 438.400, and 438.402)

As described in section II.A.2.b. of this rule, we propose to establish, for inclusion in contracts for applicable integrated plans as defined in proposed § 422.2 no later than 2021, procedures unifying Medicare and Medicaid grievances and appeals procedures in accordance with the newly enacted amendments to section 1859(f) of the Act. We also propose to establish new regulations to require all dual eligible special needs plans (D–SNPs) to assist beneficiaries with Medicaid coverage issues and grievances at § 422.562(a)(5). The proposed requirements and burden will be submitted to OMB for approval under control number 0938–0753 (CMS–R–267).

As of June 2018, the CMS website listed 190 D–SNP contracts with 412 D–SNP plans that have at least 11 members. The universe of D–SNPs to which our proposed unified grievance and appeals procedures would apply is comprised of D–SNPs that are either fully integrated dual eligible special needs plans (FIDE SNPs) or highly integrated dual eligible special needs plans (HIDE SNPs) with exclusively aligned enrollment—that is, where all of the plan's membership receives Medicare and Medicaid benefits from the same organization. Currently, exclusively aligned enrollment occurs in only eight states: Florida, Idaho, Massachusetts, Minnesota, New Jersey, New York, Tennessee, and Wisconsin. Currently, there are only 37 D–SNPs operating under 34 contracts with 150,000 enrollees that could be classified as FIDE SNPs or HIDE SNPs which operate in states with exclusively aligned enrollment. The 150,000 enrollment figure for contract year 2018 is projected to grow to 172,000 (150,000 * 1.145) [33] enrollees by 2021, the first year that compliance with these provisions would be required. While unifying grievance and appeals provisions would necessitate states with exclusively aligned enrollment policies to modify their Medicaid managed care plan contracts to incorporate the new requirements, it would impose this burden on fewer than 10 states and would not impose additional burden for plans from a contracting standpoint, thereby falling below the threshold for PRA purposes.

We believe that our proposed requirements related to integrated organization determinations and integrated grievances should not be altogether unfamiliar to applicable integrated plans because, in general terms, we have proposed to adopt whichever of the current MA D–SNP or Medicaid managed care plan contract requirements under parts 422 and 438, respectively, was more protective of the rights of the beneficiary and/or provided the most state flexibility, consistent with the statutory requirements of section 1859(f)(8) of the Act. Furthermore, we believe that by unifying Medicare and Medicaid integrated organization determination and grievance requirements for applicable integrated plans (that is, FIDE SNPs and HIDE SNPs with exclusively aligned enrollment), we are ultimately reducing the level of burden on these organizations.

The burden associated with the implementation of our proposed integrated organization determination and integrated grievance procedures is summarized in section IV.B.3.a. of this proposed rule. As detailed in IV.B.3.b. of this proposed rule, the PRA exempts the information collection activities undertaken to administer our proposed unified appeals procedures. As detailed in IV.B.3.c. of this proposed rule, we believe the requirements for all D–SNPs to assist enrollees with Medicaid coverage issues and grievances in proposed § 422.562(a)(5) is also exempt from the PRA.

[33] Table IV.C1, ''Private Health Enrollment'' in 2018 Trustee Report, accessible at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf.*

a. Integrated Organization Determinations and Integrated Grievances (§§ 422.629, 422.630, and 422.631)

Section 422.631 would require each applicable integrated plan to issue one integrated organization determination, so that all requests for benefits covered by applicable integrated plans would be subject to the same integrated organization determination process. In § 422.631(d)(1), we would require that an applicable integrated plan send an integrated notice when the organization determination is adverse to the enrollee. The proposed notice would include information about the determination, as well as information about the enrollee's appeal rights for both Medicare and Medicaid covered benefits. Though integrating information on Medicare and Medicaid appeal rights would be a new requirement, we note that requirements for a notice and the content of the notice largely align with current requirements in Medicaid (§ 438.404(b)) and MA (§ 422.572(e)). We believe that this proposed provision would have minimal impact on plans based on our understanding of how plans that would meet the definition of an applicable integrated plan under the proposed rule currently handle coverage determinations for full-benefit dual eligible individuals receiving Medicare and Medicaid services through the plan. Currently if such a plan were to deny or only partially cover a Medicaid service never covered by Medicare (like a personal care attendant or a clear request for Medicaid coverage), it would only issue a Medicaid denial (one notice). Under this proposed rule, it would do the same (that is, issue one notice). On the other hand, if the plan denied a service that is covered under either Medicare or Medicaid, such as home health services, we believe that the plan in most, if not all, states would issue an integrated determination notice that includes information about the application of Medicare and Medicaid coverage criteria to the requested service and how to appeal under both Medicare and Medicaid (one notice). This proposed rule would codify this practice for applicable integrated plans.

Also under current law, if the plan covered a service such as durable medical equipment or home health services under Medicaid, but denied the service under Medicare's rules, it would issue a Medicare denial even though the service was actually covered by the plan based on its Medicaid contract. Under this proposed rule, a plan covering both Medicare and Medicaid benefits would no longer need to issue a notice in this

situation. We do not have data to estimate the number of instances in which D–SNPs currently issue denial notices related to overlap services; therefore, we are unable to estimate the reduction in plan burden resulting from our proposed unified appeals requirements. However, we solicit feedback on the burden imposed on integrated plans by having to send such a Medicare denial notice when the service is covered by the plan under Medicaid rules. We are developing an integrated denial notice for use by applicable integrated plans. This form, and its associated requirements and burden, will be submitted to OMB for approval separately from this proposed rule once it is developed.

We estimate negligible impacts on information collection activities involved in unifying grievances associated with our proposed provisions at § 422.630, as detailed later in this section. Under § 422.630(b), applicable integrated plans would be required to accept grievances filed at any time consistent with the Medicaid standard at § 438.402(c)(2)(i). This change would have the net effect of permitting enrollees to file a grievance for a Medicare-covered service outside of the current 60-day timely filing standard, as measured from the date of the event or incident that precipitated the grievance. The provision would effectively eliminate the timely filing period for Medicare-related grievances. We do not expect this proposal to increase the volume of grievances that an applicable integrated plan would be responsible for handling since we believe that the timeframes for filing Medicare grievances were designed to be consistent with current practice and were set in place only to eliminate complaint outliers. Furthermore, as detailed later in this section, even a four-fold increase in grievance volume would still have a negligible aggregate burden because of the small number of contracts in states that currently require exclusively aligned enrollment.

Under § 422.630(c), enrollees of applicable integrated plans could file integrated grievances with the plan orally or in writing, in alignment with current Medicare and Medicaid requirements, or with the state, in states that have existing processes for accepting Medicaid grievances in place in accordance with § 438.402(c)(3). Because this proposed provision simply extends an existing avenue for filing grievances, in states where it exists, for enrollees to file Medicaid benefits grievances with the state, we do not expect this proposal to increase the volume of grievances that either states or applicable plans would be responsible for handling.

Section 422.630(d) would permit an enrollee to file an expedited grievance, which is available under current law for Medicare-covered, but not Medicaid-covered, benefits. We estimate that the availability of an expedited grievance for Medicaid benefits would have a negligible impact on information collection activities because applicable integrated plans would already have procedures in place to handle expedited grievances for Medicare-covered services, which could be leveraged for Medicaid-covered services. Furthermore, the availability of the expedited resolution pathway (where under current law there is only one resolution pathway for Medicaid-covered services) would have no impact on the volume of grievances.

Section 422.630(e)(1) would require that an applicable integrated plan resolve a standard (non-expedited) grievance within 30 days consistent with the MA standard; under Medicaid, the timeframe is established by the state but may not exceed 90 calendar days from day the plan receives the grievance. We estimate that this change in timeframe would have a negligible impact on information collection activities because applicable integrated plans already have business processes in place to comply with a 30-day timeframe under MA.

Section 422.630(e)(2) would require the applicable integrated plan, when extending the grievance resolution timeframe, to make reasonable efforts to notify the enrollee orally and send written notice of the reasons for the delay within 2 calendar days. We do not believe that this provision would have more than a negligible impact on plans since this proposal adopts MA requirements for how an applicable integrated plan must notify an enrollee of an extension and the Medicaid managed care requirement for the timeliness standard. Thus, applicable integrated plans would already have business processes in place to comply with these requirements.

Although we do not estimate cost impacts for applicable integrated plans related to information collection activities involved in unifying grievances associated with our proposed provisions at § 422.630, some of the individual provisions in §§ 422.630 and 422.631 would necessitate operational and systems changes on the part of applicable integrated plans, and others would result in savings to applicable integrated plans. We estimate both the burden and savings associated with changes to policies and procedures, record maintenance, grievance notice consolidations, and savings for our proposed integrated organization determination procedures at § 422.631 and integrated grievance procedures at § 422.630.

(1) Updates to Policies and Procedures

There would be an initial one-time burden for plans to update their policies and procedures to reflect the proposed new integrated organization determination and grievance procedures. Under §§ 422.630 and 422.631, we estimate it would take 8 hours at $69.08/hr for a business operations specialist to revise current policies and procedures. In aggregate, we estimate a one-time burden of 272 hours (8 hr * 34 contracts) at a cost of $18,790 (272 hr * $69.08/hr).

While there might be some update burden in future years, we consider this unlikely and, even if it were to occur, it would not be on the same magnitude as in the first year. We are therefore estimating a zero burden for years 2 and 3, though we acknowledge the unlikely possibility that costs could be as high as in year 1—that is, $18,790.

(2) Record Maintenance

D–SNPs, like other MA plans, are currently required to maintain records for grievances (§ 422.504(d)). However, § 422.629(h) would require the maintenance of specific data elements, consisting of a general description of the reason for the integrated grievance; the date of receipt; the date of each review or, if applicable, the review meeting; the resolution at each level of the integrated grievance, if applicable; the date of resolution at each level, if applicable; and the name of the enrollee for whom the integrated grievance was filed.

There would be an initial one-time burden for plans to revise their systems for record-keeping related to integrated grievances. We anticipate this task would take a programmer 3 hours at $81.90/hr. Three hours is consistent with the per-response time estimated in the recent Medicaid Managed Care May 2016 final rule (81 FR 27498). In aggregate, we estimate a one-time burden of 102 hours (3 hr * 34 contracts) at a cost of $8,354 (102 hr * $81.90/hr).

(3) Grievance Notice Consolidation

Section 422.630(e) would require that applicable integrated plans issue a notice upon resolution of the integrated grievance, unless the grievance was made orally and the enrollee did not request a written response. We assume in our analysis that plans issue two separate Medicare and Medicaid

grievance resolution notices under current practice when a grievance is made in writing, whereas under this proposal they would issue one consolidated notice. To calculate savings, we must add the cost of notification and the cost of grievance review.

(4) Cost of Notification

To calculate the savings due to Medicare and Medicaid notice consolidation, we utilize the following figures: (1) The number of enrollees in the exclusively aligned plans in contract year 2021, which is 172,000; (2) the time of notification using either a standard notice or a copy of the decision prepared by the reviewer (traditionally such a routine notification is estimated as 1 minute per notification (1/60 of an hour)); (3) the hourly wage for a business operations specialist; and (4) the percent of total enrollees expected to file a grievance (the recent Medicaid Managed Care May 2016 final rule (81 FR 27498) estimates a 2 percent filing rate, while the burden under OMB control number 0938–0753 (CMS–R–267) estimates 6.8 percent (17 percent of enrollees that are dissatisfied * 40 percent of dissatisfied enrollees who file a grievance)).

For purposes of specificity, we assume the average of these two estimates, 4.4 percent (½ * [6.8 percent + 2 percent]) represents the percent of enrollees filing a grievance with the integrated plan. Therefore, we estimate the annual savings due to notifications as 126 hours (1 minute * 172,000 enrollees * 0.044) at a cost of $8,704 (126 hours * $69.08/hr). The aggregate savings for years 2 and 3 are 252 hours (1 minute × 172,000 enrollees * 0.044 * 2 years) at a cost of $17,408 (252 hours * $69.08 * 2 years).

(5) Cost of Grievance Review

We assume the review will be done by a business operations specialist. Based on the Medicaid Managed Care May 2016 final rule (81 FR 21498), we assume the average grievance takes 30 minutes for a business operations specialist to resolve. Thus, the aggregate annual savings for review is 3,784 hours (172,000 enrollees * 0.044 * 0.5 hr) at a cost of $261,399 (3,784 hr * $69.08/hr). We estimate the aggregate savings for years 2 and 3 to be 7,568 hours (172,000 enrollees * 0.044 × 0.5 hr * 2 years) at a cost of $522,797, (3,784 hr * $69.08/hr * 2 years).

(6) Storage

The cost of storage is not expected to change under § 422.629(h)(3) since D–SNPs are currently required to store records (§ 422.504(d)), and the provision would not impose any new or revised storage requirements or burden.

b. Unified Appeals Procedures (§§ 422.629, 422.633, and 422.634)

The implementing regulations of the PRA at 5 CFR 1320.4 exclude information collection activities during the conduct of a civil action to which the United States or any official or agency thereof is a party, or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities. We conclude that a beneficiary's appeal of an adverse integrated coverage determination as proposed in this rule, and the subsequent information collection activities necessitated by that integrated appeal—for example, acknowledgement of integrated reconsiderations at § 422.629(g), recordkeeping related to integrated appeals at § 422.629(h), and notification of the applicable integrated plan's integrated reconsideration determination at § 422.633(f)(4)—are exempt from the PRA on the basis that an appeal is submitted in response to an administrative action against a specific individual. Therefore, this exemption would cover any information collection activities undertaken after the integrated organization determination by an applicable integrated plan.

c. Assisting With Medicaid Coverage Issues and Grievances (§ 422.562(a)(5))

We did not calculate the burden of the requirement for all D–SNPs to assist enrollees with the filing of their grievance or appeal as required in proposed § 422.562(a)(5), as we are assuming that providing assistance is a usual and customary business practice that is exempt from the PRA (5 CFR 1320.3(b)(2)).

d. Summary

The burden associated with the individual components of our proposed provisions for unified grievance and appeals procedures for applicable integrated plans, as well as aggregate cost, are summarized in Table 4A.

TABLE 4A: SUMMARY OF PROPOSED D-SNP UNIFIED GRIEVANCE AND APPEALS PROCEDURES BURDEN (OMB 0938-0753)

Item	Number of Respondents	Hours per Respondent	Total Hours	Cost per Hour	Aggregate Cost (in $), First Year	Aggregate Cost, Years 2 and 3
Updates to Policies and Procedures	34	8	272	$69.08	18,790	0
Record Maintenance	34	3	102	$81.90	8,354	0
Grievance Notice Consolidation	7,568	1/60	(378)	$69.08	(8,704)	(17,408)
Grievance Review	7,568	0.5	(11,352)	$69.08	(261,399)	(522,797)
Total	7,602	varies	(11,356)	varies	(242,959)	(540,205)

4. ICRs Regarding Proposal for Prescription Drug Plan Sponsors' Access to Medicare Parts A and B Claims Data Extracts (§ 423.153)

As described in section II.A.3. of this proposed rule, section 50354 of the Bipartisan Budget Act of 2018 requires the establishment of a process under which the sponsor of a PDP that provides prescription drug benefits under Medicare Part D may request, beginning in plan year 2020, that the Secretary provide on a periodic basis and in an electronic format standardized extracts of Medicare Parts A and B claims data about its plan enrollees. In this rule we propose to add a new § 423.153(g) to implement the process for requesting this data.

More specifically, in order to receive this data, PDP plans would be required to request the data and complete an attestation. We have not finalized the operational aspects of this provision. Therefore, this segment of the rule does not constitute a means for notice and comment as referenced in 5 CFR 1320.8(d)(3) and CMS will seek a comment through separate **Federal**

Register notices per the Paperwork Reduction Act.

5. ICRs Regarding Medicare Advantage and Part D Prescription Drug Plan Quality Rating System (§§ 422.162(a) and 423.182(a), §§ 422.166(a) and 423.186(a), §§ 422.164 and 423.184, and §§ 422.166(i)(1) and 423.186(i)(1))

As described in section III.B.1. of this proposed rule, we are proposing measure updates for the 2022 and 2023 Star Ratings, enhancements to the cut point methodology for non-CAHPS measures, and a policy for calculating the Part C and D Star Ratings when extreme and uncontrollable circumstances occur. The proposed provisions would not change any respondent requirements or burden pertaining to any of CMS's Star Ratings-related PRA packages, including: OMB control number 0938–0732 for CAHPS (CMS–R–246), OMB control number 0938–0701 for HOS (CMS–10203), OMB control number 0938–1028 for HEDIS (CMS–10219), OMB control number 0938–1054 for Part C Reporting Requirements (CMS–10261), and OMB control number 0938–0992 for Part D Reporting Requirements (CMS–10185). Since the proposed provisions would not impose any new or revised information collection requirements (that is, reporting recordkeeping, or third-party disclosure requirements) or burden, we are not making changes under any of the aforementioned control numbers.

6. ICRs Regarding Improving Clarity of the Exceptions Timeframes for Part D Drugs (§§ 423.568, 423.570, and 423.572)

The proposed provisions would not impose any new or revised information collection requirements (that is, reporting, recordkeeping, or third-party disclosure requirements) or burden. Consequently, the provisions are not subject to the PRA.

7. ICRs Regarding Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE (§§ 422.222 and 423.120(c)(6))

As described in section III.C.1. of this proposed rule, the proposed provisions would not involve activities for plan sponsors and MA organizations outside of those described in the April 2018 final rule. The proposed provisions are, generally speaking, clarifications of intended policy and would not impose any new or revised information collection requirements (that is, reporting, recordkeeping, or third-party disclosure requirements) or burden. Consequently, the provisions are not subject to the PRA.

8. ICRs Regarding Medicare Advantage Risk Adjustment Data Validation Provisions (§§ 422.300, 422.310(e), and 422.311(a))

As described in section III.C.2. of this proposed rule, we are proposing that extrapolation may be utilized as a valid part of audit authority in Part C, as it has been historically a normal part of auditing practice throughout the Medicare program. We are also proposing that this extrapolation authority be applied to the payment year 2011 RADV contract-level audits and all subsequent audits to reduce the Part C improper payment rate. Additionally, we are proposing not to apply a FFS Adjuster to audit findings.

The proposed provisions would not impose any new or revised information collection requirements (that is, reporting, recordkeeping, or third-party disclosure requirements) or burden since the utilization of extrapolation will not affect the existing process for MA organizations submitting medical record documentation pursuant to RADV audits. Consequently, the provisions are not subject to the PRA.

C. Summary of Proposed Information Collection Requirements and Burden

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TABLE 4B: ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulatory Reference	Provision Brief Title	OMB and CMS Control Numbers	Item	Respondents	Hours per Respondent	Total Hours	Cost per Hour	Total Cost, Year 1	Aggregate Cost, Years 2 and 3
§ 422.107	Integration	0938-0753 (CMS-R-267).	Initial update of States of their Contracts with D SNPs	44	24	1,056	136.44	72,040[1]	0
§ 422.107	Integration	0938-0753 (CMS-R-267).	Initial notification systems for State Medicaid Agencies	13	160	2,080	81.90	85,176[1]	0
§ 422.107	Integration	0938-0753 (CMS-R-267).	Initial notification systems for State Medicaid Agencies	13	160	2,080	69.08	71,843[1]	0
Subtotal (State Burden)				*57*	*Varies*	*5,216*	*Varies*	*229,059*	*0*
§ 422.107	Integration	0938-0753 (CMS-R-267).	Initial updates of D-SNPs of their Contracts with the State	116	8	928	136.44	126,616	0
§ 422.107	Integration	0938-0753 (CMS-R-267).	Initial notification of D-SNPs to Medicaid Agencies	116	160	18,560	81.90	1,520,064	0
						18,560	69.08	1,282,125	
§§ 422.630 and 422.631	Unified Appeals and Grievances	0938-0753 (CMS-R-267).	Initial Update on Grievance Procedures	34	8	272	69.08	18,790	0
§§ 422.630, and 422.631	Unified Appeals and Grievances	0938-0753 (CMS-R-267).	Record Maintenance	34	3	102	81.90	8,354	n/a
§§ 422.630, and 422.631	Unified Appeals and Grievances	0938-0753 (CMS-R-267).	Notification Requirements	7,568	(0.0167)	(126)	69.08	(8,704)	(17,408)
§§ 422.630, and 422.631	Unified Appeals and Grievances	0938-0753 (CMS-R-267).	Grievance Review Requirements	7,568	(0.5)	(3,784)	69.08	(261,399)	(522,797)
Subtotal				*15,436*	*Varies*	*34,512*	*Varies*	*2,685,846*	*540,205*
Total				*15,493*	*Varies*	*39,728*	*Varies*	*2,914,905*	*540,205*

NOTE: Reflects 50 percent reduction to Federal Matching program.

D. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to the Office of Management and Budget (OMB) for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections previously discussed, please visit CMS's website at: *https://www.cms.gov/Regulations-andGuidance/Legislation/PaperworkReductionActof1995/PRAListing.html,* or call the Reports Clearance Office at (410) 786–1326.

We invite public comments on these proposed information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule and identify the rule (CMS–4185–P) and where applicable the ICR's CFR citation, CMS ID number, and OMB control number.

See the **DATES** and **ADDRESSES** sections of this proposed rule for further information.

IV. Regulatory Impact Analysis

A. Statement of Need

This rule proposes to implement specific provisions of the Bipartisan Budget Act of 2018 related to additional telehealth benefits, MA dual eligible special needs plans (D–SNPs), and Part D sponsors' access to Medicare claims data. The rule also proposes to improve quality and accessibility; clarify certain program integrity policies; reduce burden on providers, MA organizations, and Part D sponsors through providing additional policy clarification; and implement other technical changes regarding quality improvement. Although satisfaction with the MA and Part D programs remains high, these proposals are responsive to input we received from stakeholders while administering the programs, as well as through our requests for comment. CMS decided to modify the MA and Part D Prescription Drug Plan Quality Rating System in response to comments from the proposed rule entitled Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, The Medicare Prescription Drug Benefit Programs, and the PACE program (November 28, 2017, 82 FR 56336).

In this proposed rule, we are proposing policies to continue to drive affordable private plan options for Medicare beneficiaries that meet their unique healthcare needs, such as through supporting innovation in telehealth among MA plans to provide more options and additional benefits for MA enrollees. These proposed provisions align with the Administration's focus on the interests and needs of beneficiaries, providers, MA plans, and Part D sponsors.

B. Overall Impact

We examined the impact of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act (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).

The RFA, as amended, requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions.

This proposed rule affects MA plans and Part D sponsors (NAICS category 524114) with a minimum threshold for small business size of $38.5 million (*http://www.sba.gov/content/small-business-size-standards*). This proposed rule additionally affects hospitals (NAICS subsector 622) and a variety of provider categories, including physicians and specialists (NAICS subsector 621).

To clarify the flow of payments between these entities and the federal government, note that MA organizations submit bids (that is, proposed plan designs and projections of the revenue needed to provide those benefits, divided into three categories—basic benefits, supplemental benefits, and Part D drug benefits) in June 2019 for operation in contract year 2020. These bids project payments to hospitals, providers, and staff as well as the cost of administration and profits. These bids in turn determine the payments from the Medicare Trust Fund to the MA organizations that pay providers and other stakeholders for their provision of covered benefits to enrollees. Consequently, our analysis will focus on MA organizations.

There are various types of Medicare health plans, including MA plans, Part D sponsors, demonstrations, section 1876 cost plans, prescription drug plans (PDPs), and Program of All-Inclusive Care for the Elderly (PACE) plans. Forty-three percent of all Medicare health plan organizations are not-for-profit, and 31 percent of all MA plans and Part D sponsors are not-for-profit. (These figures were determined by examining records from the most recent year for which we have complete data, 2016.)

There are varieties of ways to assess whether MA organizations meet the $38.5 million threshold for small businesses. The assessment can be done by examining net worth, net income, cash flow from operations, and projected claims as indicated in their bids. Using projected monetary requirements and projected enrollment for 2018 from submitted bids, 32 percent of the MA organizations fell below the $38.5 million threshold for small businesses. Additionally, an analysis of 2016 data—the most recent year for which we have actual data on MA organization net worth—shows that 32 percent of all MA organizations fall below the minimum threshold for small businesses.

If a proposed rule may have a significant impact on a substantial number of small entities, the proposed rule must discuss steps taken, including alternatives, to minimize burden on small entities. While a significant number (more than 5 percent) of not-for-profit organizations and small businesses are affected by this proposed rule, the impact is not significant. To assess impact, we use the data in Tables 18 A and B, which show that the raw (not discounted) net effect of this proposed rule over 10 years is $20.8 million. Comparing this number to the total monetary amounts projected to be needed just for 2020, based on plan submitted bids, we find that the impact of this rule is significantly below the 3 to 5 percent threshold for significant impact. Had we compared the 2020 impact of the proposed rule to projected 2020 monetary need, the impact would be still less.

Consequently, the Secretary has determined that this proposed rule will not have a significant economic impact on a substantial number of small entities, and we have met the requirements of the RFA. In addition, section 1102(b) of the Act requires us to prepare a regulatory analysis for any final rule under title XVIII, title XIX, or Part B of Title XI of the Act that may have significant impact on the

operations of a substantial number of small rural hospitals. We are not preparing an analysis for section 1102(b) of the Act because the Secretary certifies that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of UMRA also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2018, that threshold is approximately $150 million. 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 $150 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Since this proposed rule does not impose any substantial costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

If regulations impose administrative costs on reviewers, such as the time needed to read and interpret this proposed rule, then we should estimate the cost associated with regulatory review. There are currently 750 MA contracts (which also includes PDPs), 50 State Medicaid Agencies, and 200 Medicaid Managed Care Organizations (1,000 reviewers total). We assume each entity will have one designated staff member who will review the entire rule. Other assumptions are possible and will be reviewed after the calculations.

Using the wage information from the Bureau of Labor Statistics (BLS) for medical and health service managers (code 11–9111), we estimate that the cost of reviewing this rule is $107.38 per hour, including fringe benefits and overhead costs (*http://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it will take approximately 12.5 hours for each person to review this proposed rule. For each entity that reviews the rule, the estimated cost is therefore, $1,342 (12.5 hours * $107.38). Therefore, we estimate that the total cost of reviewing this regulation is $1,342,000 ($1,342 * 1000 reviewers).

Note that this analysis assumed one reader per contract. Some alternatives include assuming one reader per parent entity. Using parent organizations instead of contracts would reduce the number of reviewers to approximately 500 (assuming approximately 250 parent organizations), and this would cut the total cost of reviewing in half. However, we believe it is likely that reviewing will be performed by contract. The argument for this is that a parent organization might have local reviewers; even if that parent organization has several contracts that might have a reader for each distinct geographic region, to be on the lookout for effects of provisions specific to that region.

In accordance with the provisions of Executive Order 12866, this rule was reviewed by the Office of Management and Budget (OMB).

C. Anticipated Effects

1. Requirements for Medicare Advantage Plans Offering Additional Telehealth Benefits (§§ 422.100, 422.135, 422.252, 422.254, and 422.264)

As stated in the preamble, section 50323 of the Bipartisan Budget Act of 2018 allows MA plans to provide ''additional telehealth benefits'' to enrollees starting in plan year 2020 and treat them as basic benefits for purposes of bid submission and payment by CMS. We propose to codify requirements at § 422.135, which would authorize and set standards for MA plans to offer additional telehealth benefits. The proposed regulation has the following impacts.

There are two primary aspects of the proposed additional telehealth provision that could affect the cost and utilization of MA basic benefits, with a corresponding impact on Medicare program expenditures. The most direct effect is the reclassification of certain telehealth services covered by MA plans pre-Bipartisan Budget Act of 2018 from supplemental benefits to basic benefits. This change will lead to higher basic benefit bids, as the cost of additional telehealth benefits will be included in the development of the basic benefit bid. The impact on the basic benefit bid may be muted due to the exclusion of capital and infrastructure costs and investments related to additional telehealth benefits from the bid.

Prior to estimating the impact on the bid, we point out several other sources of impact. Many studies have argued that telehealth will increase utilization of medical services by making them more accessible. However, the increased utilization could lead to increased savings or cost. The increased utilization could lead to significant savings due to prevention of future illness. Alternatively, the increased utilization could lead to increased costs if enrollees start seeing doctors for complaints on which they did not traditionally seek medical advice. We cite below studies for each possibility. Additionally, if there are increased telehealth visits, providers may request increased face-to-face visits to protect themselves from liability.

Consequently, there are four potential impacts of this provision, which we discuss in more detail later in this section. The four areas are as follows:

- Impact on the Medicare Trust Fund
- Savings for Enrollees due to Decreased Travel Time to Providers
- Savings from Illness Prevention due to Increased Access to Services
- Increased Costs if Unnecessary Medical Visits Increase

Because of the wide variability in potential impact, we solicit comments on best practices in telehealth and the resulting savings.

a. Impact on the Medicare Trust Fund

Superficially, there appears to be no program change since the provision simply reclassifies certain benefits as basic instead of supplemental. Thus, the same benefits are provided. However, a closer look at the language and assumptions of the provision show that, while collectively additional telehealth benefits will yield a negligible change in program spending, there is a small transfer of costs (0.002 percent of the MA baseline) from enrollees to the Medicare Trust Fund, associated with reclassifying these benefits from supplemental to basic benefits. Supplemental benefits are generally paid with rebates while basic benefits are paid by a capitation rate, calculated with reference to the bid. For the plans to provide benefits through rebates requires additional funding since the amount of rebates provided by the Medicare Trust Fund averages only $0.66 on the dollar. Thus, the effect of this provision is that either the enrollee pays a lower supplemental premium or receives richer supplemental benefits. In either case, the enrollee saves and the Medicare Trust Fund incurs a cost. It follows that this provision creates a transfer from enrollees to the Medicare Trust Fund. After accounting for infrastructure costs, and backing out the Part B premium, the extra cost to the Medicare Trust Fund is projected to be $80 million over 10 years. The calculations for the first 10 annual estimates are presented in Table 6 of this rule and discussed in the narrative.

In order to estimate the 10-year impact (2020 through 2029) of the proposed additional telehealth benefits provision on the Medicare Trust Fund, we considered the following six factors.

• We first estimated the costs of additional telehealth benefits that are to be transferred from supplemental benefits to basic benefits. Using the 2019 submitted bid information, we estimated that $0.09 per member per month (pmpm) would be transferred. We computed $0.09 by examining and averaging the largest organizations' telehealth benefits, particularly under the category ''Web and Phone Based Technology.'' The reason for basing estimates on the largest organizations is that only the largest organizations included the category ''Web and Phone Based Technology'' as a separate line item in their bids. The other organizations had multiple, non-telehealth benefits, in the same line as the telehealth benefits, and so we were not able to distinguish the costs between telehealth and non-telehealth for the smaller organizations. Information from the 2018 Medicare Trustees Report [34] shows that the applicable medical-inflation trend that should be applied to the $0.09 pmpm is 5.2 percent per year; the average trend can be derived from information in Table IV.C3 of this report.

• We applied the pmpm amounts to the projected MA enrollment for the years 2020 through 2029. The source of the projected MA enrollment is Table IV.C1 of the 2018 Medicare Trustees Report.

• We assumed that 15 percent of the additional telehealth benefits would be considered capital and infrastructure expenses. As discussed in the preamble, these expenses are excluded from the Medicare Trust Fund payments for additional telehealth benefits. We obtained the 15 percent assumption by subtracting the 85 percent required Medical Loss Ratio (MLR) from 100 percent. We used the MLR as a proxy for the medical share of provider payments.

• We applied the average rebate percentage of 66 percent, which is based on the expected submitted bid information, including expected enrollment and expected average Star Ratings.

• We applied a factor of 86 percent to the calculation, which represents the exclusion or the backing out of the Part B premium.

• However, per OMB guidance, ordinary inflation should be carved out of estimates, while medical inflation, which outpaces ordinary inflation (as well as enrollment growth), may be retained. The source of the ordinary inflation is Table IV.D1 of the 2018 Medicare Trustees Report. It is 2.6 percent per year for each of the years 2020 through 2029.

Combining these six factors, we calculated the net costs to the Medicare Trust Fund to be $6.1 million in 2020, $6.5 million in 2021, $6.9 million in 2022, $7.3 million in 2023, and $7.7 million in 2024. We calculated the net costs to the Medicare Trust Fund for years 2025 through 2029 to be $8.2 million, $8.5 million, $9.0 million, $9.5 million, and $9.9 million, respectively. The calculations of impact for 2020 through 2029 are summarized in Table 6. The total cost for all 10 years is found in the right-most column of Table 6, titled ''Net Costs.''

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[34] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf.*

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TABLE 5: CALCULATIONS OF NET COSTS PER YEAR TO THE MEDICARE TRUST FUND FOR ADDITIONAL TELEHEALTH BENEFITS

Year	Enrollment (thousands)	PMPM Cost	Number of Months per Year	Gross Amount ($ in millions) (A)	Infrastructure Costs (B)	Average Rebate Percentage (C)	Backing out of Part B Premium (D)	Net Cost ($millions) (A * (1-B) * (1-C) * (D) * (E))	Ordinary Inflation (F)	Net Costs ($millions) (A * (1-B)) * (1 - C) * (D) (E)/ (1+(F))^(year-2019)
2020	21,995	0.09	12	25.0	15%	66%	86%	6.2	2.6%	6.1
2021	22,873	0.10	12	27.3	15%	66%	86%	6.8	2.6%	6.5
2022	23,739	0.10	12	29.8	15%	66%	86%	7.4	2.6%	6.9
2023	24,584	0.11	12	32.5	15%	66%	86%	8.1	2.6%	7.3
2024	25,395	0.12	12	35.3	15%	66%	86%	8.8	2.6%	7.7
2025	26,198	0.12	12	38.4	15%	66%	86%	9.5	2.6%	8.2
2026	26,986	0.13	12	41.6	15%	66%	85%	10.2	2.6%	8.5
2027	27,737	0.14	12	44.9	15%	66%	85%	11.0	2.6%	9.0
2028	28,455	0.14	12	48.5	15%	66%	85%	11.9	2.6%	9.5
2029	29,101	0.15	12	52.2	15%	66%	85%	12.8	2.6%	9.9
Raw Total										79.6

b. Savings for Enrollees Due to Decreased Travel Time to Providers

Additional telehealth benefits will save enrollees the cost of traveling to providers. Currently, original Medicare telehealth benefits are used to bring healthcare services to MA enrollees, including those in rural locations. Stakeholders have informed CMS that MA enrollees like the use of telehealth services to reduce travel times and have greater access to providers that may not otherwise be available.

The analysis assumes a replacement of some face-to-face provider visits with telehealth visits and no additional increase in overall provider visits. Although, as discussed later in this section, there are studies suggesting the possibility of increased provider visits due to ease of access of telehealth, these studies are mainly theoretical and furthermore suggest methods to curb the unwanted increase in visits; it might therefore, be very reasonable to assume that there is no increase. Another important point to bear in mind is that increased telemonitoring does not cost the enrollee extra time. Once a system is set up to electronically transfer medical measurements, the enrollee does not have to spend extra time for this transmission. A provider will only intervene if a medical measurement indicates the possibility of an adverse medical event. However, in such a case, the expected adverse medical event might be resolvable with a phone call or medication adjustment and is less costly time-wise than an actual face-to-face provider visit.

An additional concern with this estimation is that it does not take into account that the current MA program already has certain telehealth benefits, such as phone hotlines and telemonitoring. Therefore, it is not accurate to estimate the effect of telehealth in general without differentiating the former allowance of telehealth and the new allowances afforded by this provision.

We believe that the primary driver of telehealth savings is not the authority under the law to use it, but rather, increased availability of telehealth technology and implementation. For example, although current MA guidelines allow some telehealth services as supplemental benefits, only the largest plans have provided specific, line item data on it in their bid submissions.

Another example, illustrating that availability, not authority under the law, is the primary driver of telehealth savings, is found in national usage of telehealth. Although telehealth has always been allowed by commercial plans, it is rapidly increasing now because of increased availability and ease of implementation. Studies continually point to the growth potential for using telehealth; these studies emphasize that telehealth is not being used where it could be and that the issues are feasibility and availability.[35]

Thus, allowing plans to offer additional telehealth benefits, or reclassify their current supplemental telehealth benefits as basic benefits, would not, by itself, increase telehealth usage. Rather, the increased telehealth usage comes when telehealth technologies are readily available and easy to implement. The goal of this provision is to foster an atmosphere where both commercial and MA plans will be equally interested in the increasingly accessible technology and seek to incorporate it in their offerings.

In summary, we acknowledge the possibility that the estimates below, assuming no increase in provider visits and not taking into account current telehealth practices, may have elements of overestimation. Because of our uncertainties, we invite industry comments on our analysis.

To estimate the impact on enrollee travel time, we need four estimates:

- *Average travel time and average travel distance per visit:* While it is difficult to estimate the savings in reduced travel time quantitatively, since distances from enrollees to providers vary significantly, to estimate the travel time to providers we use a former CMS standard that providers should be located within 30 minutes or 30 miles of each enrollee. While this standard has since been replaced by a more sophisticated measurement of access, we can use it as a proxy. The former CMS standard was used because it is formulated simply in terms of time (one-half hour) and miles (30 miles) and does not differentiate among provider types. The current standards for access involve sophisticated algorithms, which involve more than two parameters (time and mileage), and additionally differ by geographic location and provider types. Therefore, the current standards were not suitable. We therefore assume that the midpoint, 15 minutes or 0.25 hour, represents the typical travel time to providers per enrollee visit.[36] We similarly believe that 15 miles (one-half of 30 miles) is the average travel distance per provider visit. We note the group of individual respondents varies widely from working and nonworking individuals and by respondent age, location, years of employment, and educational attainment. CMS estimates cost per hour for enrollees using the occupational title ''All Occupations'' (occupation code 00–0000) from the BLS, with a mean wage of $24.34/hour. Thus, the net savings per enrollee per telehealth visit to providers would be $17.57 ($24.34 hourly wage * 0.25 minutes travel time * 2 (round trip) + 15 miles * 2 (round trip) * 18 cents a mile (cost of gasoline for medical transportation [37])). This is summarized in Table 7.
- *Average number of visits per enrollee:* The Center for Disease Control (CDC) estimates that in 2014, 65-year-olds and older average 5.89 visits per person.[38]
- *Number of MA enrollees:* Table IV.C1 of the 2018 Medicare Trustees Report provides the projected MA enrollment.
- *Percent, per year, of provider visits that are telehealth:* Ideally, we would like an estimate on the number of total visits and telehealth visits for 65-year-olds. However, these data are not available. Therefore, we use the best available proportions. We proceed as follows.

The CDC website cited above estimates 885 million provider visits in 2014. This is an aggregate number over all age groups; the 885 million was not broken out further by age group.

Absent information on the proportion of telehealth visits among total visits by 65-year-olds to providers, we use general averages (across all age groups) with the understanding that some accuracy is lost. The Statista website suggests 22 million telehealth visits in 2014.[39] This implies that 2.49 percent (22/885) of all physician visits were for telehealth.

Inferring growth rates from the numbers on the Statista website, the projected low and high growth rate for telehealth services is 1.089 percent and 1.22 percent respectively. Other

[35] See *https://www.ncbi.nlm.nih.gov/pubmed/23406075.* Also see Harry Wang, Director Health and Mobile Product Research, Parks Associates ''Virtual Health Care will revolutionize the Industry If we let it'', Forbes, 2014, accessible at *https://www.forbes.com/sites/ciocentral/2014/04/03/virtual-health-care-visits-will-revolutionize-the-industry-if-we-let-it/#4ee9a9e97c25.*

[36] This would result in 30 minutes (2 * 15 minutes) roundtrip. The following article using independent sources estimates 37 minutes, which is close to our estimate: *https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.1130.*

[37] *https://www.irs.gov/newsroom/standard-mileage-rates-for-2018-up-from-rates-for-2017.*

[38] *https://www.cdc.gov/nchs/products/databriefs/db292.htm.*

[39] *https://www.statista.com/statistics/820756/number-of-telehealth-visits-in-us/.*

websites give similar ranges. For example, in three places Becker gives three estimates for telehealth growth rates of 14.3 percent, 16.5 percent, and 27.5 percent.[40] Because of this variability, we use the lower estimate for projected telehealth growth, which is about 1.089 percent. These numbers can be used to estimate the proportion of provider visits that will be telehealth in future years. For example, in 2015, we assume 1.089 (growth rate) * 2.49 percent (proportion of provider visits that are telehealth in 2014) = 2.71 percent of provider visits will be telehealth visits.

Multiplying these four numbers together—average savings per visit ($17.57) * visits per enrollee (5.89) * number of MA enrollees * percent of provider visits that are telehealth (2.49 percent * 1.089 per year)—we arrive at a conservative estimate of $60 million, growing to $100 million in 2024, and $170 million in 2029. Had we used the higher projected visits, we would have obtained $60 million, growing to $540 million. The results are summarized in Table 8.

We emphasize that these results have a tendency toward underestimation for the following reasons:

- We have only estimated the impact on physician visits and have not taken into account telehealth surgery and telemonitoring.
- We have assumed an 8.9 percent growth rate.
- We have applied the growth rate in telehealth for all age groups to the 65 and older population.

On the other hand, we have not carved out current MA telehealth utilization (an overestimating effect). However, we believe this is a good starting point for estimation of savings to enrollees. In other words, the use of the 2.49 percent estimate, above, would be reasonable if MA enrollees currently have negligible access to telehealth and then, as a result of this proposed rule, begin using telehealth at a rate similar to the national average. However, there is presently some telehealth coverage in MA, so the preceding method most likely yields a substantial overestimate of the impact of the telehealth provision, and thus the results are used for illustrative purposes only. As such, we welcome comments, especially from groups that have data relevant to 65-year-olds, on the rule-induced incremental use of telehealth.

These illustrative estimates do not reflect the possible effect of increased unnecessary medical visits, that is, medical visits made because of the ease of access of telehealth in situations when enrollees normally would not seek medical care. We discuss our rationale in section IV.C.1.d. of this proposed rule.

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[40] See *https://www.beckershospitalreview.com/healthcare-information-technology/telemedicine-to-attract-7m-patient-users-by-2018-12-statistics-on-the-thriving-market.html; https://www.beckershospitalreview.com/telehealth/global-telemedicine-market-to-experience-16-5-annual-growth-rate-through-2023.html*; *https://www.beckershospitalreview.com/healthcare-information-technology/the-growth-of-telehealth-20-things-to-know.html.*

TABLE 7: TRAVEL SAVINGS PER PROVIDER VISIT, TELEHEALTH

Label	Item	Amount	Source
(A)	One way travel to provider	0.25 hours	Former CMS standard of provider availability within 30 minutes (we use midpoint of 30 and 0 minutes, or 15 minutes). An alternative source cited above suggests 18.5 minutes one way.
(B)	Travel to and from provider	2	
(C)	Wages for enrollee per hour	$24.34	OMB guidance, use of occupational code 00-0000 on BLS website
(D)	Mileage cost per mile for medical travel	$0.18	IRS website
(E)	Mileage	15 miles	Former CMS standard of provider availability within 30 miles (we use midpoint of 30 and 0 miles, or 15 miles).
(F)	Wage savings per provider visit	$12.17	(A) * (B) * (C)
(G)	Mileage savings per provider visit	$5.40	(A) * (E) * (D)
	Total savings per visit	$17.57	(F) + (G)

TABLE 8: ILLUSTRATION OF POTENTIAL TRAVEL SAVINGS PER YEAR, TELEHEALTH

Year	Total Savings (in millions) to Enrollees in Travel time from Telehealth	MA Enrollment	Savings per Telehealth Visit	Provider Visits per Enrollee	Percentage of Provider Visits that use Telehealth
2020	$59.7	23,181	$17.57	5.89	2.49%
2021	$67.5	24,062	$17.57	5.89	2.71%
2022	$76.2	24,972	$17.57	5.89	2.95%
2023	$85.9	25,858	$17.57	5.89	3.21%
2024	$96.7	26,708	$17.57	5.89	3.50%
2025	$108.7	27,549	$17.57	5.89	3.81%
2026	$121.9	28,375	$17.57	5.89	4.15%
2027	$136.4	29,161	$17.57	5.89	4.52%
2028	$152.4	29,913	$17.57	5.89	4.92%
2029	$169.7	30,590	$17.57	5.89	5.36%

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c. Savings From Illness Prevention Due to Increased Access to Services

Telehealth savings due to increased prevention may arise from easier access to services. The additional telehealth benefits to be included in the MA basic benefit bid stem from the Bipartisan Budget Act of 2018 amendment of section 1852 of the Act. These services will likely represent a mix of replacement of pre-Bipartisan Budget Act of 2018 face-to-face encounters and additional services. We believe that increased coverage of the additional telehealth benefits will generally result in an aggregate reduction in use of emergency room visits and inpatient admissions because the relative increased ease of receiving healthcare services should improve health outcomes and reduce avoidable utilization that results from untreated conditions exacerbating illness. Several studies predict that telehealth can significantly reduce illness through prevention. We mention four areas: (1) Healthcare management; (2) medication therapy management (MTM); (3) transitional care programs; and (4) post-hours telemonitoring.

(1) Healthcare Management

Telehealth has been shown to increase efficiency through better healthcare management.[41] MA enrollees who choose telehealth are better able to manage their conditions through the use of technology for treatment plan management and medication management. Treatment often involves changes to the patient's lifestyle, such as weight management, smoking cessation, and dietary changes. Using technology to conduct lifestyle counseling remotely makes it more likely that the provider and patient will work collaboratively on the treatment plan.

(2) Medication Therapy Management (MTM)[42]

Additionally, telehealth can help significantly with patients who need multiple medications. Remote medication management can reduce the multiple patient visits often necessary to get the appropriate mix of medications. One recent meta-study on MTM summarizes seven studies, showing that using comprehensive medication reviews (the principle driver of MTM savings) reduced hospitalizations, readmissions, drugs, and mortality.[43]

[41] Armaignac, Donna Lee, Saxena, Anshul, Rubens, Muni, Valle, Carlos, Williams, Lisa-Mae, Veledar, Emir, and Gidel, Louis (2018). ''Impact of Telemedicine on Mortality, Length of Stay, and Cost Among Patients in Progressive Care Units: Experience From a Large Healthcare System.'' Critical Care Medicine, 46(5): 728–735.

[42] Our current MA program allows telemonitoring, hospital readmission prevention programs, and post-discharge in home medication reconciliation.

[43] Evan A. DeZeeuw, PharmD; Ashley M. Coleman, PharmD; and Milap C. Nahata, PharmD, MS, ''Impact of Telephonic Comprehensive Medication Reviews on Patient Outcomes,'' Am J Manag Care. 2018;24(2):e54–e58.

(3) Transitional Care Programs

Telehealth has been used to provide transitional care for discharged hospital patients. One study found a savings of $1,333 per beneficiary, half of which was due to reduced inpatient follow-up care.[44]

(4) Post-Hours Telemonitoring

A study reviewing after-hours telemedicine (in which a nurse would transmit data about patients with a change in condition) reported savings of $4,000 per skilled nursing facility bed, which translates into savings of $5 million against a cost of $1 million for implementing the program.[45]

d. Increased Costs if Unnecessary Medical Visits Increase

There are two primary concerns regarding telehealth savings.[46] The first concern is that the direct-to-consumer telehealth visits are more likely to result in follow-up appointments, testing, or prescriptions. Compared to similar visits to other settings, direct-to-consumer telehealth could increase spending (by MA plans, providers, the government, and/or patients). For example, given liability concerns, direct-to-consumer telehealth physicians may be more likely to recommend that patients have a subsequent in-person visit with a provider. Therefore, although the telehealth visit is less costly, the per-episode cost of a direct-to-consumer telehealth visit could be greater than that of a visit in other settings.

The second concern is that the convenience of direct-to-consumer telehealth may drive many patients to seek care for an illness when they would not have sought care if telehealth had not been available. Instead of saving money by substitution (that is, replacing more expensive visits to physician offices or emergency departments), direct-to-consumer telehealth may increase spending by new utilization (that is, increasing the total number of patient visits).

To document these concerns, the Health Affairs article cited above presents a study on commercial health plan enrollees with specific illnesses. The study showed an increase of $45 per year per telehealth user. The authors acknowledge that a key attraction of telehealth for commercial health plans and employers is the potential savings involved in replacing physician office and emergency department visits with less expensive virtual visits; however, increased convenience may tap into unmet demand for health care, and new utilization may increase overall healthcare spending.

The article acknowledges various limitations of the study: (1) It applies to commercial health plan enrollees; (2) only one telehealth company in California was used; (3) the users had a low telehealth usage, and study results could differ if telehealth becomes more popular; and (4) only one medical condition was studied (which is frequently dealt with by telehealth).

The article also mentions various approaches that could be used to reduce extra costs, for example, increasing cost sharing to prevent indiscriminate use of telehealth on conditions that one would not ordinarily see a provider.

In conclusion, although telehealth has a significant potential to produce savings, this potential is counterbalanced by several factors, which might reduce these savings or produce increased costs for MA plans, providers, the government, and/or patients (such as increased in-person visits and increased utilization patterns). Additionally, several telehealth services—telemonitoring and remote access technologies (including web/phone based hotlines)—are allowed under current guidelines; many MA plans already offer these services as supplemental benefits.

As regards to the illustrative calculation of a $6 to $10 million transfer from enrollee to government and a savings to enrollees of $60 to $100 million per year, arising from reduced travel times, we now summarize the simplifying assumptions below.

First, the transfer from enrollee to government reflects an assumption that the same number of services will occur, but their classification will change from supplemental to basic. This simplifying assumption is certainly contradicted by the expected growth rate in telemonitoring. However, we have argued above that increased use of telemonitoring will result in significant healthcare savings due to prevention of future illnesses. Therefore, a $6 to $10 million estimate of cost per year may be outweighed by healthcare savings.

Second, the savings of $60 to $100 million per year arising from reduced travel time to providers reflects several simplifying assumptions such as applying proportions of telehealth services of provider visits in the general population to the aged population and ignoring the current extent of telehealth services in MA plans.

Thirdly, we have disregarded the possible cost impact of telehealth arising from enrollees indiscriminately using telehealth for provider services in situations where provider assistance was not previously sought. As noted previously, this negative effect was found in one commercial provider on a population with a very low telehealth usage. Furthermore, there are possible methods to prevent indiscriminate use of telehealth services. The majority of the articles we cited and reviewed previously were very positive about health savings and did not mention increased costs. Therefore, we determined the best approach is to assume the increased costs from telehealth will not arise.

Fourth, we ignore the current usage of telehealth by MA plans who may furnish telehealth as a supplemental benefit. Our primary reason for ignoring this is the lack of adequate data. Other reasons for ignoring this are that only large plans have listed supplemental telehealth as a line-item in their bid documentation, and articles generally show that even where allowed (such as in commercial plans) telehealth is not used to its full potential.

In light of the information provided previously, all our estimates of impact should be seen as reasonable first attempts at estimation with the intent to solicit comments from the industry on their experiences and whether such assumptions are warranted or should lead to modifications in our estimates.

There is one additional negligible cost, mentioned in section III.B.1. of this proposed rule, which arises from the proposed provision at § 422.135(c)(2) requiring that MA plans advise enrollees that they may receive the specified Part B service(s) either through an in-person visit or through electronic exchange. This notification would appear in the Evidence of Coverage (EOC) document, which is already required and provided in model form by CMS to MA plans. There is a one-time cost for CMS staff to formulate the required template notification language in our EOC model for all plans to adopt without edit.

We estimate it would take a CMS Central Office staff person 1 hour to

[44] Keith Kranker, Ph.D.; Linda M. Barterian, MPP; Rumin Sarwar, MS; G. Greg Peterson, Ph.D.; Boyd Gilman, Ph.D.; Laura Blue, Ph.D.; Kate Allison Stewart, Ph.D.; Sheila D. Hoag, MA; Timothy J. Day, MSHP; and Lorenzo Moreno, Ph.D. ''Rural Hospital Transitional Care Program Reduces Medicare Spending,'' Am J Manag Care. 2018;24(5):256–260.

[45] David Chess, MD; John J. Whitman, MBA; Diane Croll, DNP; and Richard Stefanacci, DO ''Impact of After-Hours Telemedicine on Hospitalizations in a Skilled Nursing Facility,'' The Amer. J. of Manage Care, 24(8), 2018, e54–e56.

[46] J. Scott Ashwood, Ateev Mehrotra, David Cowling, and Lori Uscher-Pines, ''Direct-To-Consumer Telehealth May Increase Access To Care But Does Not Decrease Spending,'' Health Affairs, Vol. 36, No. 3: Delivery System Innovation, accessible at *https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.1130.*

produce language for such a model. The typical Central Office employee is at the GS–13 level. The 2018 wages for the Baltimore area, available at *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2018/AK_h.pdf,* indicate an approximate hourly wage of $50 (with the Step 3 hourly wage being slightly below and the Step 4 hourly wage being slightly above). We further allow 100 percent for fringe benefits and overhead costs. Thus, the expected burden to the federal government is a negligible cost of $100 (1 hour * $50 wage per hour * 2).

2. Integration Requirements for Dual Eligible Special Needs Plans (§§ 422.2, 422.60, 422.102, 422.107, 422.111, and 422.752)

As stated in the preamble, starting in 2021, section 50311(b) of the Bipartisan Budget Act of 2018 establishes new Medicare and Medicaid integration standards for MA organizations seeking to offer D–SNPs and enrollment sanctions for those MA organizations that fail to comply with the new standards. We propose to add a revised definition for ''D–SNP'' at § 422.2 and establish at § 422.107 revisions to the existing minimum state Medicaid agency contracting requirement for D–SNPs other than FIDE SNPs and HIDE SNPs, which are also defined at § 422.2.

As noted in the preamble, many of the changes we are proposing would unify and streamline existing requirements, which should reduce burden and are therefore not expected to have impact. For example:

- *Passive enrollment:* The reference to the proposed definition of a HIDE SNP at § 422.2 would not materially change the plan types that are eligible for passive enrollment; rather, the existing rule simply refers to them as the D–SNPs that meet a high standard of integration under the supplemental benefit authority at § 422.102(e).
- *Enhanced Supplemental Benefits:* We also propose clarifying at § 422.102(e) that not only are HIDE SNPs that meet minimum quality and performance standards eligible to offer supplemental benefits, but FIDE SNPs that similarly meet minimum quality and performance standards may do so as well. While this amendment does not change what has occurred in practice, we believe it clarifies the types of plans that are eligible to offer enhanced supplemental benefits.

Additional costs were presented in the Collection of Information (COI) section of this proposed rule. However, the COI made an assumption which must be modified for purposes of this Regulatory Impact Analysis (RIA) section: The cost to State Medicaid agencies for updating their contracts was reduced by 50 percent reflecting the Federal administrative matching rate for state Medicaid agency expenditures. This is correct for the COI since federal costs are never listed in the COI. However, for the purposes of the RIA section they should be listed. More specifically, the total cost should be listed as a true cost (that is payment for services and goods) to the state agencies, half of which is transferred to the federal government. The simplest way to describe the impact of this provision is simply to redo the summarizing table in the COI section. The assumptions and sources underlying the numbers in this table have been presented in the COI section. This is presented in Table 9.

Table 9 notes which numbers are true savings or costs and which numbers or parts of estimates are transfers. Since the impacts are for services such as updating manuals or updating software, the cost and savings impact are true costs or savings (which in some cases reflect a transfer to the federal government). Table 9 also notes who bears the cost (states or MA plans). As can be seen, the aggregate cost of this provision is a first year cost of $3.4 million, $0.2 million of which are transfers between the Federal government and states. As noted in the section, although additional updates may be necessary in future years, we are scoring this as $0 as a best estimate given uncertainty regarding the need for additional changes by states and plans after the first year.

TABLE 9: COST OF INTEGRATION

Item	Respondents	Hours per Respondent	Total Hours	Cost per Hour	Total Cost	Nature of Cost Impact. To Whom and Whether True Impact or Transfer.
Initial update by state Medicaid agency of its contracts with D-SNPs*	44(States)	24	1,056	$136.44	$144,081	50% true cost of services to state; 50% transfer to Federal government
Initial update by D-SNPs of their contracts with the state Medicaid agency	116 (D-SNPs)	8	928	$136.44	$126,616	True cost of services to MA Plans
Initial establishment of system for notification of hospital and skilled nursing facility admissions by state Medicaid agency*	13 (States)	160	2,080	$81.90	$170,352	50% true cost of services to State; 50% transfer to Federal government
	13(States)	160	2,080	$69.08	$143,686	50% true cost of services to State; 50% transfer to Federal government
Initial notification of hospital and skilled nursing facility admissions by D-SNPs to state Medicaid agency	116(D-SNPs)	160	18,560	$81,90	$1,520,064	True cost of services to MA Plans
	116 (D-SNPs)	160	18,560	$69.08	$1,282,125	True cost of services to MA Plans
Total	Varies	Varies	43,264	Varies	$3,386,924	

3. Unified Grievance and Appeals Procedures for Dual Eligible Special Needs Plans and Medicaid Managed Care Plans at the Plan Level (§§ 422.560–562, 422.566, 422.629–634, 438.210, 438.400, and 438.402)

Proposed changes to the appeals and grievances provisions at §§ 422.629 through 422.634 focus on creating MA and Medicaid appeal and grievances processes that are unified for D–SNPs that also have comprehensive Medicaid managed care contracts (or are the subsidiary of a parent organization or share a parent organization with the entity with a comprehensive Medicaid managed care contract). The proposal addresses appeals at the plan level. Currently, Medicaid and MA appeals and grievance processes differ in several key ways. These differences hinder a streamlined grievance and appeals process across Medicare and Medicaid managed care sectors and create unnecessary administrative complexity for plans that cover dual eligible individuals for both Medicare and Medicaid services. Our proposed revisions would allow enrollees in a D–SNP that is also a Medicaid managed care plan through which the enrollees get Medicaid coverage to better understand the grievance and appeals processes and generally receive a resolution of their grievances and appeals more quickly.

There are six areas where this provision will have an impact.

- Certain Medicare Parts A and B benefits that the D–SNP has tried to terminate would be provided during the pendency of the integrated appeal at the plan level. This is estimated in detail below. The cost to the Medicare Trust Fund and beneficiaries (in the form of cost sharing) is $0.4 million in 2021 and $0.5 million in 2022–2024, growing modestly due to expected enrollment growth, to $0.6 or $0.7 million in the next few years.
- Applicable integrated plans' grievance policies and procedures and grievance notices would be updated. As discussed in the Collection of Information section, there would be a one-time first year cost of $18,790 for updates of applicable integrated plans' policies and procedures on grievances and an annual savings of $270,103 reflecting savings from Medicare and Medicaid grievance consolidation). Thus, there would be an annual savings of $0.3 million.
- Notice templates for the unified appeals for use by applicable integrated plans would be created by CMS, which is estimated to be a one-time negligible cost of about $1,000 for the work of Federal employees.
- Subregulatory guidance on integrated grievance and appeals would be developed by CMS staff, which is estimated to be a one-time negligible cost of about $2,000.
- Applicable integrated plans' appeals policies and procedures and appeals notices would be updated to comply with the unified appeals requirements, which is estimated to be a one-time negligible cost of $9,395 (4 hours per contract * 34 contracts * $69.08, the hourly wage of a business operations specialist).
- Enrollees of applicable integrated plans who wish to receive a copy of their appeal case file would request that plans send it to them at plan expense, which we estimate to cost about $38,637 annually.

The aggregate cost of this provision is $0.2 million a year. Industry would save $0.3 million each year in reduced services because grievances in Medicare and Medicaid are unified. However, this $0.3 million savings would be offset by an increase in cost of $0.5 million reflecting increased services. The $0.5 million cost (as well as the 0.3 million savings) are ultimately borne by the Medicare Trust Fund in the form of payments and beneficiaries in the form of increased cost-sharing.

We present details on these six areas in the sections that follow.

a. Furnishing Medicare Parts A and B Services During the Pendency Of Appeals

One of the provisions related to appeals integration may marginally impact the ways MA sponsors bid for their D–SNPs, which could marginally impact Medicare spending. We propose that the existing standards for continuation of benefits at § 438.420 apply to applicable integrated plans for Medicare benefits under Parts A and B and Medicaid benefits in our proposed integrated appeals requirements at § 422.632. Under our proposal, and as is applicable to Medicaid managed care plans currently, if an applicable integrated plan decides to stop or reduce a benefit that the enrollee is currently authorized to receive, the enrollee could request that the benefit continue to be provided at the currently authorized level while the enrollee's appeal is pending through the integrated reconsideration. Currently, MA plans in general are not required to provide benefits pending appeal, whereas in Medicaid it has been a long-standing feature.

It is our expectation that the new integrated appeals provisions will result in an increase in expenditures by applicable integrated plans for Medicare covered services because they will be required to continue coverage for services during the pendency of the reconsideration request, or first-level appeal under our proposal.

The estimate of impact of this continuation is based on calendar year (CY) 2016 appeal metrics, which are then trended to CY 2021.

The assumptions, sources and calculations are summarized in Tables G5 and G6 in this rule and further clarified as follows.

The first step in this estimation is to determine the number of applicable reconsiderations per 1,000 beneficiaries enrolled in integrated plans affected by this provision. Given the similarity of population characteristics, the reconsideration experience for the Medicare-Medicaid Plans (MMPs) participating in the Financial Alignment Initiative was used as a proxy for the applicable integrated plans. In 2016, MMP enrollees were impacted by 1,232 reconsiderations for services which were resolved adversely or partially favorably to the beneficiary. The corresponding MMP enrollment in 2016 was 368,841, which implies a rate of 3.3 applicable reconsiderations per 1,000 in 2016.

Then we projected D–SNP enrollment impacted by the unified procedures to grow from 150,000 in 2018 to 172,000 (150,000 * 1.145) in 2021 based on the estimated enrollment growth for all D–SNPs during the period of 14.5 percent. Applying the MMP appeal rate of 3.3 per 1,000 to the projected 2021 enrollment in applicable integrated plans of 172,000 results in an estimated 568 (172,000 * 3.3/1,000) service reconsiderations for the applicable integrated plans in 2020.

The next step is to determine the average level of benefit subject to the appeals. Table 1 in the report Medicare Part C QIC Reconsideration Data for 2016 [47] contains data on the number and benefit amounts by service category for the second level appeals filed in 2016. Analysis of these data resulted in an estimated per-appeal benefit value of $737 for 2016. The determination of this value took into account that some services would not be subject to the regulatory extension of coverage due to the existence of immediate review rights (inpatient hospital, skilled nursing facility, and home health), other benefits would likely have been rendered already (emergency room, and ambulance), and other services are not

[47] *https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/IRE.html.*

covered as a D–SNP basic benefit (hospice and non-Medicare benefits). Accounting for 19.5 percent inflation in per-capita Medicare spending between 2016 and 2021, and carving out the 13.38 percent consumer price index inflation in years 2016—2020 inclusive, results in an estimated per-appeal benefit value of $774 (that is, $737 * 1.195/1.1338) for 2021.

Taking the product of the number of applicable integrated plan service reconsiderations in 2021 (568) and average benefit value in 2021 ($774) yields an estimated cost in 2021 of $439,632 (that is, 568 * $774) due to an increase in Medicare expenditures stemming from the unified appeals procedures for applicable integrated plans. We believe that this figure represents an upper bound of the cost given that not all applicable services will be rendered during the extended period of benefit continuation being proposed in this regulation. These calculations are summarized in Table 10.

Using the 2021 estimates as a basis, estimates for 2021 through 2029 are presented in Table 11. The following assumptions were used in creating Table 11:

- As described earlier in this section, the numbers in the row for 2021 come from Table 10.
- The projected FIDE SNP enrollment for 2022 through 2029 was obtained by multiplying the estimated 2021 FIDE SNP enrollment of 172,000, using SNP enrollment growth factors inferred from Table IV.C1 in the 2018 Trustees Report.
- The projected cost per appeal for 2022 through 2029 was obtained by first multiplying the estimated 2021 cost per appeal of $774 by FFS per capita growth rates obtained from internal documentation for the Table of FFS USPCC, non-ESRD estimates in attachment II of the 2019 Rate Announcement and Call Letter (*https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf*).

The results are summarized in Table 11. As can be seen, there is an estimated true cost (reflecting purchase of goods and services) of $0.4 million in 2021 and $0.5 million in 2022 through 2024. Eighty-six percent of this cost is transferred from the plans to the Medicare Trust Fund. The remainder of this cost is born by beneficiary cost sharing. The cost of appeals between 2025 and 2029 is $0.5 to 0.6 million for the Medicare Trust Fund and $0.1 million for beneficiaries.

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TABLE 10: IMPACT OF INTEGRATED APPEALS PROVISION OF FIDE SNPS

Row ID	Item Description	Number	Data Source
	MMP Appeals: 2016		
(A)	Appeals	1,232	2016 Parts C and D Reporting Requirements PUF (not incl. Part D MTM data) from site https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartCDDataValidation.html Sum of service reconsiderations partially favorable and adverse for organization type "Demo"
(B)	Enrollment	368,841	2016 Parts C and D Reporting Requirements PUF (not incl. Part D MTM data) from site https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartCDDataValidation.html Sum of enrollment for organization type "Demo"
(C)	MMP appeals per 1000	3.3	(C) =(A) / (B) * 1000
	FIDE SNP Appeals 2021		
(D)	Enrollment 2018	150,000	Internal CMS enrollment extract in HPMS data system for July 2018
(E)	DE SNP enrollment growth: '18-'21	14.5%	Table IV.C1, "Private Health Enrollment" in 2018 Trustee Report, accessible at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf
(F)	Enrollment 2021	172,000	(F) = (D)*(1+(E))
(G)	MMP Appeals per 1000 in 2016	3.3	Row (C)
(H)	FIDE SNP appeals 2021	568	(H) = (F)/1000 * (G)
	Cost of FIDE SNP Appeals: CY 2021		
(I)	Average benefit per appeal (2016)	$737	Data obtained from CMS Appeal & Grievance Contractor
(J)	Inflation: 2016 – 2021	19.5%	Ratio of CY 2021 and CY 2016 entries in table "Comparison of Current and Previous Estimates of the FFS USPCC - Non ESRD" in the 2019 Rate Announcement and Call letter accessible at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf
(K)	Carving out Ordinary Inflation 2016-2021	13.80%	Product of the urban consumer price index (CPI-U) increase factors for 2016-2020 inclusive. Data were obtained from Table V.B2 in the 2017 CMS Trustee Report accessible at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2017.pdf
(L)	Average benefit per appeal (2021)	$774	(L) = (I) * (1 + (J)) / (1+(K))
(M)	Aggregate amount of appeal (2021)	$440,000	(M) = (L) * (H)

TABLE 11: NET COST PER YEAR TO THE MEDICARE TRUST FUND FOR INTEGRATED PLAN APPEALS

Contract Year	Affected FIDE SNP Enrollment (A)	Appeals per 1,000 Affected Enrollees (B)	Number of Affected Appeals per Year (C) = (A) / 1000* (B)	Cost per Appeal (D)	Gross Cost of Appeals (millions $) (E) = (D)*(C)/ 1,000,000	Share of cost funded by Medicare Trust Funds (F)	Net Cost of Appeals to Medicare Trust Fund (millions $) (F)*(E)	Net Cost of Appeals to Beneficiaries (1-F)*(E)
2021	172,000	3.3	568	$774	$0.4	86%	$0.4	$-----
2022	179,000	3.3	591	$791	$0.5	86%	$0.4	$0.1
2023	185,000	3.3	611	$808	$0.5	86%	$0.4	$0.1
2024	191,000	3.3	630	$828	$0.5	86%	$0.4	$0.1
2025	197,000	3.3	650	$842	$0.5	86%	$0.5	$0.1
2026	203,000	3.3	670	$861	$0.6	85%	$0.5	$0.1
2027	209,000	3.3	690	$883	$0.6	85%	$0.5	$0.1
2028	215,000	3.3	710	$903	$0.6	85%	$0.5	$0.1
2029	220,000	3.3	726	$920	$0.7	85%	$0.6	$0.1

b. Updating Plan Grievance Policies and Procedures and Consolidation of Plan Notifications

As detailed in the Collection of Information section of this proposed rule, there are only 34 contracts representing 37 D–SNPs that we currently believe would be classified as a HIDE SNP or FIDE SNP and operate in states that have policies requiring exclusively aligned enrollment across MA and Medicaid managed care plans. The analysis presented in the Collection of Information section for unified grievance and appeals estimates initial one-time cost of $18,790 and $8,374 and annual savings, due to reduction of notifications, of $270,103. Thus, the annual savings is $0.2 million in the first year and $0.3 million annually thereafter.

c. Creation of New Grievance and Appeal Notice Templates

When MA plans send out notifications to enrollees, they usually have the option to use templates created by CMS. To address the proposed new unified grievance and appeal procedures, CMS Central Office staff must create new notice templates. We estimate that three new notice templates must be created. We estimate each new template will require 3 hours of work by a GS level 13, step 5 (GS–13–5), employee. The 2018 hourly wages for a GS–13–5 Federal employee is $52.66.[48] We allow 100 percent for Fringe Benefits and overtime. Thus the expected one-time negligible initial cost is $1,000 (actually, $948 = 3 templates * 3 hours per template * $52.66 hourly wage * 2 for overtime and fringe benefits).

d. Subregulatory Guidance in CMS Manuals on the New Grievance and Appeals Procedures

The CMS manuals present comprehensive sub-regulatory guidance on regulatory matters. Since these unified grievance and appeals procedures are new, we estimate it would require 20 hours to develop subregulatory guidance to be published in the CMS Medicare managed care manual. Thus we expect a negligible one-time cost of $2,000 (actually $2,106 = 20 hours of work * $52.66, hourly wage for a GS–13–5 * 2 for overtime and fringe benefits).

e. Updating Applicable Integrated Plan Appeals Policies and Procedures

Applicable integrated plans' internal appeals policies and procedures must be updated to comply with the unified appeals requirements. In terms of updates, we see no reason to differentiate between the work required for grievances and appeals. Using our estimate for grievance procedures, we estimate for appeals an initial one-time negligible cost of $9,395 (that is, 4 hours per contract * 34 contracts * $69.08, the hourly wage of a business operations specialist including 100 percent for fringe benefits and overhead).

f. Sending Appeal Files to Enrollees Who Request Them

Medicaid managed care regulations currently require plans to send, for free, appeal case files to enrollees who appeal while, in contrast, MA regulations require sending such files at a reasonable cost. Our proposal would require the applicable integrated plans to send such files for free. To estimate this cost, we must first estimate the cost of sending such a file.

Livanta,[49] a Quality Improvement Organization, estimates the cost per case file as $40–$100. This can be justified independently with a stricter range as follows: Assuming a typical case file has 100 pages, it would weigh about 1 pound at 6 pages per ounce. The cost of mailing a 1-pound case file by FedEx (to assure security) is $10. The cost of photocopying 100 pages at a minimum rate of $0.05 per page is $5. The $0.05 per page is likely to be an overestimate for plans that own their own photocopying equipment. Thus, the total cost of photocopying and mailing would be about $15. We assume a correspondence clerk, BLS occupation code 43–4021,[50] would take 1 hour of work, at $36.64 per hour (including 100 percent for overtime and fringe benefits) to retrieve the file, photocopy it, and prepare it for mailing. Thus we estimate the total cost at $36.64 + $10 + $5 = $51.64.

We need further estimates to complete the calculation. We assume 43.5 total appeals (favorable and unfavorable) per 1000.[51] Based on our experience, we assume that 10 percent of all appeals would require a file sent. Finally, as indicated in the Collection of Information section, there are 37 D–SNPS in 34 contracts with 150,000 enrollees in 2018 projected to grow to 172,000 enrollees in 2021. Thus we estimate the total annual cost of mailing files to enrollees as $38,637 (that is, 172,000 enrollees * 4.35 percent appeals

[48] *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2018/DCB_h.pdf.*

[49] *https://bfccqioareal.com/recordrequests.html.*

[50] *https://www.bls.gov/oes/current/oes_nat.htm.*

[51] *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartCDDataValidation.html.*

* 10 percent requesting files * $51.64 cost).

In conclusion, the primary driver of costs of this provision are the effects on the Medicare Trust Fund and beneficiary cost sharing presented in Tables G5 and G6. These costs are offset by annual savings of $0.3 million due to unification of grievance procedures. Other costs are considered negligible (below a $50,000 threshold for E.O. 13773 accounting). A summary by year is presented in Table 12.

TABLE 12: SUMMARY OF COSTS (MILLIONS) FOR GRIEVANCE INTEGRATION PROVISION

	Unification of Grievance Procedures	Cost to Medicare Trust Fund	Cost Sharing for MA Enrollees	Total
2020	----	-----		0
2021	(0.2)	$0.4	$------	0.2
2022	(0.3)	$0.4	$0.1	0.2
2023	(0.3)	$0.4	$0.1	0.2
2024	(0.3)	$0.4	$0.1	0.2
2025	(0.3)	$0.5	$0.1	0.3
2026	(0.3)	$0.5	$0.1	0.3
2027	(0.3)	$0.5	$0.1	0.3
2028	(0.3)	$0.5	$0.1	0.3
2029	(0.3)	$0.6	$0.1	0.4

We note that these costs and savings are true costs and savings since they reflect payment for additional or fewer economic resources (reduced notifications and increased appeals). The increased appeals costs are a cost to MA plans, which transfer this cost to enrollees and the Medicare Trust Fund (the government).

4. Proposal for Prescription Drug Plan Sponsors' Access to Medicare Parts A and B Claims Data Extracts (§ 423.153)

As described in section II.A.3. of this proposed rule, section 50354 of the Bipartisan Budget Act of 2018 requires the establishment of a process under which the sponsor of a PDP that provides prescription drug benefits under Medicare Part D may request, beginning in plan year 2020, that the Secretary provide on a periodic basis and in an electronic format standardized extracts of Medicare claims data about its plan enrollees. In this rule we propose to add a new § 423.153(g) to implement the process for requesting these data.

To estimate the impact we require a model of operationalizing this provision, without however committing to a particular operationalizing process. We outline a process which—

- Meets all regulatory requirements; and
- Requires as little burden as possible to make and grant requests.

We solicit comments from stakeholders on this proposed operationalization.

Electronic request and transfer are superior (have less burden) than paper processes. We could therefore add functionalities to the CMS HPMS system (or other CMS systems) which would allow the following functions:

- Request of claims data for the current and future quarters for enrollees of the PDP requesting the data.
- Request to no longer receive data.
- Attestation that all regulatory requirements will be complied with. The attestation would be in the form of a screen listing all regulatory requirements; the authorized PDP HPMS user would have to electronically attest by clicking a button.

Such a process would combine request and attestation. The receipt of the submission would verify completeness of request. Furthermore, there would be no burden in request (under 1 minute of work).

The HPMS contractors estimate that this would be a one-time update costing approximately $200,000.

Besides requesting the data, data must be transmitted to the requesting sponsor. Ideally, data would be transmitted electronically but we do not yet have such an API. Instead, we would treat requested data like data requested for research. Typically, such data is downloaded onto hard drives and mailed to requestors.

The data could come from the Chronic Condition Warehouse (CCW). We asked our contractors the cost of downloading quarterly such data and sending it out. The cost varies by sponsor size. Currently, based on CMS public data, there are 63 PDP sponsors. Their size and the quarterly cost per sponsor of providing them with data, should they request it, is summarized in Table 13.

TABLE 13: COST PER PDP SPONSOR PER QUARTER FOR TRANSMITTING CLAIMS DATA

PDP Size in Enrollees	Number of Sponsors	Cost per Quarter per Sponsor for Transmission of Claims Data
Above 5 million	1	$26,500
1 million – 5 million	6	$17,500
100,000 – 1 million	11	$10,500
Under 100,000	45	$10,500

To complete the annual impact analysis we need an estimate of proportions for each plan size that would request data. For example, we are certain that the 1 PDP sponsor with over 5 million enrollees will request data. Thus the annual burden for that plan size is 1 * 4 quarters X $26,500 per quarter = $106,000. Similarly, if we assume that all six PDP sponsors with enrollments between 1 and 5 million would request data then the annual burden is 6 sponsors * 4 quarters * $17,500 per quarter per sponsor = $420,000. If we assume that only three-quarters of these six sponsors request data then the annual burden would be 0.75 * $420,000 = $315,000. In the absence of any other basis for the decision, it is reasonable to assume that the proportion goes down as the size goes down. In the absence of data, we could use a descent of simple fractions (1, three-fourths, one-half, one-fourth). Note, that 50 percent of plans with under 100,000 enrollees have under 10,000 enrollees. It is very unlikely that such plans would have the resources to use the data. Thus an assumption that only 50 percent of plans under 100,000 request data is reasonable. However, we consider multiple scenarios. Table 14 presents for a variety of scenarios of proportions and their total impact. The average of the five scenarios is $1.5 million while the median is $1.3 million. The range of impacts is $0.8 million–$2.9 million. For purposes of E.O. 13771 accounting we are listing the impact as $1.5 million annually, with a $0.2 million one-time cost in the first year. We do not trend this estimate by year since the number of PDP sponsors has remained at 63 since 2015.

TABLE 14: ANNUAL BURDEN OF PROVIDING CLAIMS DATA TO PDP SPONSORS

Scenario Label	Proportion of sponsors with over 5 million enrollees requesting data	Proportion of sponsors with 1 - 5 million enrollees requesting data	Proportion of sponsors with 100,000 – 1 million enrollees requesting data	Proportion of sponsors with under 100,000 enrollees requesting data	Aggregate annual burden based on Costs provided in Table 13
A	100 percent	75 percent	50 percent	33 percent	$1.3 million
B	100 percent	100 percent	75 percent	50 percent	$1.8 million
C	100 percent	50 percent	33 percent	25 percent	0.9 million
D	100 percent	100 percent	100 percent	100 percent	$2.9 million
E	100 percent	100 percent	50 percent	0 percent	$0.8 million

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We do not anticipate any further burden. It is most likely that the PDP sponsor would exclusively use the data. In the event that downstream entities are shared any data they are already bound in their contracts by all Medicare regulations including the regulations of this provision. Even if there would be a need to modify contracts to address the regulatory requirements of using such data, it would require at most one hour of work of a GS–12 or GS–13 staff member and one hour of review by a GS–15. A total of 2 hours of work by Federal employees would have a burden significantly less than $1,000. Hence, we are not further scoring this negligible impact.

5. Medicare Advantage and Part D Prescription Drug Plan Quality Rating System (§§ 422.162(a) and 423.182(a), §§ 422.166(a) and 423.186(a), §§ 422.164 and 423.184, and §§ 422.166(i)(1) and 423.186(i)(1))

We are proposing some measure specification updates. These type of changes are routine and do not have an impact on the highest ratings of contracts (that is, overall rating for MA–PDs, Part C summary rating for MA-only contracts, and Part D summary rating for stand-alone prescription drug plans). Hence, there will be no, or negligible, impact on the Medicare Trust Fund.

We are also proposing some adjustments for disasters. The proposed policy would make adjustments to take into account the potential impact on contracts when there are extreme and uncontrollable circumstances affecting them. This policy is in response to the multiple disasters in 2017 and 2018, including several hurricanes and wildfires. We are proposing a policy to permit an adjustment to Star Ratings when extreme and uncontrollable circumstances occur during the performance period or measurement period for MA and Part D plans.

We are also proposing enhancements to the current methodology to set Star Ratings cut points. The intent of the changes is to increase the stability and predictability of cut points from year to year. This proposal is consistent with the CMS goal to increase transparency. We believe this provision would also have minimal impact on the highest ratings of contracts. Specifically, simulations of the proposal using the 2018 Star Ratings show that the QBP

ratings overall would increase for less than 1 percent of MA enrollees.

6. Improving Clarity of the Exceptions Timeframes for Part D Drugs (§§ 423.568, 423.570, and 423.572)

We are proposing to limit the amount of time an exception request can be held open to 14 calendar days, meaning that there will be an outside limit to how long the request is in a pending status while the Part D plan sponsor attempts to obtain the prescribing physician's or other prescriber's supporting statement. Under current manual guidance, plan sponsors are instructed that an exception request should only be held open for a reasonable period of time if a supporting statement is needed. We believe that no more than 14 calendar days is a reasonable period of time to have an exception request open and this proposal seeks to codify that standard. We do not expect this proposal to have any new impact on the number of pending appeals or pose a potential burden to plan sponsors, as we expect plans are already making and notifying enrollees of decisions on exception requests under a similar reasonable timeframe. Based on findings from plan sponsor audits, this proposed timeframe is generally consistent with how plans sponsors have operationalized the current standard that cases only be held open for a reasonable period of time pending receipt of a prescriber's supporting statement. Therefore, we do not expect that plan sponsors would need to hire more staff or adjust their operations in a manner that would affect costs. Consequently, we expect the impact of this proposed requirement to be negligible.

7. Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE (§§ 422.222 and 423.120(c)(6))

We do not anticipate any additional cost or savings associated with our proposed preclusion list provisions. As we indicated in section III. of this proposed rule, the proposed provisions would not involve activities for plan sponsors and MA organizations outside of those described in the April 2018 final rule. Our proposed provisions are, generally speaking, clarifications of our intended policy and do not constitute new requirements. Hence, the expected impact is negligible.

8. Medicare Advantage Risk Adjustment Data Validation Provisions (§§ 422.300, 422.310(e), and 422.311(a))

a. Proposals

This proposed rule would create regulations to govern the collection of *extrapolated* audit findings. As CMS develops its approach to statistical sampling and extrapolation, it is taking account of the recommendations of the 2016 General Accounting Office (GAO) report on CMS audit practices.[52] For example, CMS has been randomly selecting 30 plans for audit based on factors unrelated to payment error. In recent years, only half of those audited plans have had findings; the other half have had no net findings of improper payments. The GAO has recommended that CMS select plans that historically have high error rates either from the National audits as published in the Report of the Chief Financial Officer or from prior CMS audits. This recommendation would probably increase the number of findings, and hence the amount collected through the audits. CMS has accepted all GAO findings and intends to develop its sampling and extrapolation methodology consistent with them.

To clarify in more detail how the proposed rules would impact the recovery audit process we note the following facts:

- RADV recovery for payment years 2011, 2012, and 2013 included 30 MA contracts per payment year. For each contract, 200 enrollees have been selected. The aggregate cost to the government for each audit is $54 million.
- National audits are for the purpose of payment error measurement in the Part C program. A nationally representative sample of 600 enrollees are selected from approximately 200 plans. Each plan contributes between 1 to 15 enrollees with many plans contributing under 10 enrollees. The annual cost to the government of a national audit is between $6 to 10 million. No recovery is made through the national audits.
- Findings from the national and contract-level audits will be used to predict beneficiaries at most risk for improper payment. CMS will use these estimates to target plans at most risk for improper payment for RADV audit.
- By better targeting audits to improper payment, CMS expects any sentinel effect of RADV to continue to reduce the historical Part C error rate.

b. Expected Impact of These Provisions

While we cannot fully estimate the quantitative impact of this provision, we can clearly identify certain components of impact. We start with some basic facts mentioned in the preceding narrative.

- With extrapolated audit findings, we would realize a positive ROI. The cost per year for a RADV audit is $54 million. Non-extrapolated recoveries would result in a $10 to 15 million collection per audit.
- Extrapolating audit findings does not increase the cost burden on the plan. The cost to the plan of complying with a RADV audit is neither the subject of nor affected by this provision. This provision addresses recovering extrapolated or non-extrapolated audit findings. While extrapolation does increase the level of the audit recovery, because returning improper payments is not a cost, the decision to extrapolate does not impact the cost to the plan.
- The audits for payment years 2011, 2012, and 2013 suggest that audited MA contracts received $650 million in of improper payments in those 3 years.
- This $650 million would be a transfer from the government to insurers since money paid for human coding error which CMS paid the contracts to pay their providers is no longer being done, meaning that the contracts must take responsibility for the improper provider payments.
- These audits cover 3 years, with 30 contracts audited each year.
- Roughly half the contracts each year had no net findings of improper payments.

Using these data we can conclude as follows:

- The audits for payment years 2011, 2012, and 2013 suggest that audited MA contracts were responsible for $650 million of improper payments in those 3 years.
- $650 million divided by 3 audit years is $217 million per audit year.
- $217 million per audit year divided by 15 contracts with audit findings per year is $14.5 million per contract with audit findings per year.
- If GAO recommendations are adopted which would facilitate focusing on contracts with expected findings, and the level of audit findings holds constant, then $14.5 million per contract with audit findings per year times 30 contract with audit findings per year would produce $435 million in audit collections per year.
- This level of recovery would produce $381 million in aggregate savings per year (that is, $435 million − $54 million, since the cost of audits would remain at $54 million).

This numerical bulleted argument is summarized in Table 15.

It might seem natural to trend the $381 million based on non-inflation factors. The following considerations argue against trending. Therefore, we are leaving the estimate of dollar savings

[52] *https://www.gao.gov/products/GAO-16-76.*

to the Medicare Trust Fund at $381 million per year at each year for the next 10 years with an additional $650 million the first year. A 10-year table is presented in Table 16. The arguments against trending are the following:

- The error rate of improper payments per year, as indicated in the reports of the Chief Financial Officer have been declining and are likely to continue to decline. Importantly, although we have about 10 years of data we have insufficient data to extrapolate since performance error is rarely linear. Thus trending would involve non-linear functions and would require more data.
- The aggregate amount paid to contracts is increasing due to enrollment growth. The Office of the Actuary at CMS annually publishes a Trustee Report which contains projected enrollment.[53]
- The $381 million is based on current error rates and enrollment growth. But we have already indicated that 50 percent of contracts audited had no net audit findings. We have already indicated that acceptance of GAO recommendations would facilitate targeting contracts with higher rates and have therefore assumed there would be findings in all 30 contracts audited.

For these reasons, we are leaving the annual estimate as a dollar savings to the Medicare Trust Fund of $381 million for 2021 and future years, and a dollar savings of $1.03 billion to the Medicare Trust Fund in 2020 ($381 million savings per year plus an estimated $650 million in audit recoveries for payment years 2011 through 2013). All other things being equal, the increase in enrollment will cause the nominal dollars in error to increase. The historical decline in the error rate may or may not offset the increase due to increasing enrollment making a projection difficult. For this reason we hold the estimate of $381 million constant in the projection.

A table of collection for 10 years is summarized in Table 16.

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[53] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/index.html.*

TABLE 15: EXPECTED SAVINGS PER YEAR FROM RADV PROVISION

Label	Item	Amount ($ in millions)	Source or Calculation
(A)	Estimated Collection 2011-2013	$650	
(B)	Number of years, 2011-2013	3	
(C)	Estimated Collection per year, 2011-2013	$217	(C) = (A)/(B)
(D)	Number of contracts audited	30	
(E)	Percent of contracts with findings	50%	
(F)	Current Number of contracts with findings	15	(F) = (D)*(E)
(G)	Estimated Collection per year per contract	$14.5	(G)=(C)/(F)
(H)	Expected number of contracts with findings	30	If GAO report recommendations are adopted
(I)	Estimated collection per year	$435	(I)=(G)*(H)
(J)	Audit Cost per year	$54	Constant cost of auditing 200 beneficiaries per contract.
(K)	Estimated savings per year	$381	(K)= (I) - (J)

TABLE 16: IMPACT PER YEAR FROM RADV (IN MILLIONS)

	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
Cost of Audit	(54)	(54)	(54)	(54)	(54)	(54)	(54)	(54)	(54)	(54)
Estimated Collection Prior Years	650	0	0	0	0	0	0	0	0	0
Estimated Collection This year	435	435	435	435	435	435	435	435	435	435
Estimated Total Savings	1031	381	381	381	381	381	381	381	381	381

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The estimated 10-year dollar savings to the Medicare Trust Fund could be $4.5 billion ($381 million per year * 10 years + initial $650 million recovery).

The savings come from recovered inaccurate payments of $381 million a year by the Medicare Trust Fund to plans. This money is a reduction in spending of the Medicare Trust Fund (to the plans); there will be no money transferred to enrollees. We expect that ultimately this provision could incentivize plans to submit more accurate risk-adjustment data.

The intent of this rule is to continue the sentinel effect on the reduction of the Part C error rate. The decline in the Part C error rate has correlated with the announcement of the agencies intent to use extrapolated recoveries on payment years 2011 through 2013. We believe that forgoing the extrapolation on those audits would diminish the agency's credibility going forward and consequently reduce the sentinel effect. The dollar savings to the Medicare Trust Fund are presented in Table 16. In any case, RADV audits will still continue.

D. Alternatives Considered

1. Requirements for Medicare Advantage Plans Offering Additional Telehealth Benefits (§§ 422.100, 422.135, 422.252, 422.254, and 422.264)

Section 1852(m)(2)(A)(i) of the Act, as added by the Bipartisan Budget Act of 2018, defines additional telehealth benefits as services that are identified for the applicable year as clinically appropriate to furnish using electronic information and telecommunications technology when a physician (as defined in section 1861(r) of the Act) or practitioner (described in section 1842(b)(18)(C) of the Act) providing the service is not at the same location as the plan enrollee (which we refer to as ''through electronic exchange''). We considered various alternative definitions of ''clinically appropriate'' but decided not to propose specific regulation text defining the term. We are proposing to implement the statutory requirement for additional telehealth benefits to be provided only when ''clinically appropriate'' to align with existing CMS rules for contract provisions at § 422.504(a)(3)(iii), which requires each MA organization to agree to provide all benefits covered by Medicare ''in a manner consistent with professionally recognized standards of health care.''

The statute does not specify who or what entity identifies the services for the year. We considered various alternatives, including retaining the authority as an agency to specify what services are clinically appropriate to furnish each year. MA plans could have been required to comply with an annual list of clinically appropriate services identified by CMS. However, we rejected this alternative as too restrictive; we believe MA plans are in the best position and it is in their own interest to stay abreast of professional standards necessary to determine which services are clinically appropriate. Thus, we are proposing to interpret this provision broadly by not specifying the Part B services that an MA plan may offer as additional telehealth benefits for the applicable year, but instead allowing MA plans to independently determine which services each year are clinically appropriate to furnish in this manner. Our proposed definition of additional telehealth benefits at § 422.135(a) provides that it is the MA plan (not CMS) that identifies the appropriate services for the applicable year.

We also considered alternatives to implement how telehealth benefits are provided through ''electronic exchange.'' CMS considered defining the specific means of ''electronic exchange.'' However, we decided to define ''electronic exchange'' at § 422.135(a) as ''electronic information and telecommunications technology,'' as the former is a concise term for the latter, which is the statutory description of the means used to provide the additional telehealth benefits. We are not proposing specific regulation text that defines or provides examples of electronic information and telecommunications technology. We considered providing a complete list of means of providing electronic information and telecommunications technology. Although we provided examples of electronic information and telecommunications technology in the preamble, we did not provide a comprehensive list because the technology needed and used to provide additional telehealth benefits will vary based on the service being offered. We believe this broad approach will avoid tying the authority in the proposed new regulation to specific information formats or technologies that permit non-face-to-face interactions for furnishing clinically appropriate services.

2. Integration Requirements for Dual Eligible Special Needs Plans (§§ 422.2, 422.60, 422.102, 422.107, 422.111, and 422.752)

We propose to require D–SNPs that—(1) do not meet the HIDE SNP or FIDE SNP integration standard; and (2) do not have a parent organization assuming clinical and financial responsibility for Medicare and Medicaid benefits to notify the state Medicaid agency or its designee when a high-risk full-benefit dual eligible enrollee has a hospital or skilled nursing facility admission. We considered several alternatives to this proposal, as explained in section II.A.2.a.(2). of this rule, including examples provided in the Bipartisan Budget Act of 2018: Notifying the state in a timely manner of enrollees' emergency room visits and hospital or nursing Home discharges; assigning each enrollee a primary care provider; and data sharing that benefits the coordination of items and services under Medicare and Medicaid. However, we believe our proposal is preferable to the alternatives when considering the degree to which it meets our criteria of—(1) meaningfully improving care coordination and care transitions and health outcomes for dually eligible beneficiaries; (2) minimizing burden on plans and states relative to the improvements in care coordination and transitions; (3) providing flexibility to state Medicaid agencies; (4) enabling CMS to assess compliance with minimal burden on CMS, plans, and providers; and (5) adhering to the letter and spirit of the Bipartisan Budget Act of 2018. However, we soliciting comment on these alternatives.

3. Unified Grievance and Appeals Procedures for Dual Eligible Special Needs Plans and Medicaid Managed Care Plans at the Plan Level (§§ 422.560, 422.562, 422.566, 422.629 through 422.634, 438.210, 438.400, and 438.402)

We propose to create unified grievance and appeals procedures for certain D–SNPs (FIDE SNPs and HIDE SNPs) with exclusively aligned enrollment, which we propose defining as occurring when such a D–SNP limits enrollment to full-benefit dual eligible individuals whose Medicaid benefits are covered by the D–SNP itself, or by a Medicaid managed care organization that is the same organization, the D–SNP's parent organization, or another entity that is owned and controlled by the D–SNP's parent organization. Because most D–SNP enrollees are not enrolled in D–SNPs with exclusively aligned enrollment, we considered the feasibility of broadening the scope of these unified procedures to apply to more D–SNPs—that is, to D–SNPs without exclusively aligned enrollment. However, in most states, the majority of D–SNP enrollees have Medicaid coverage either through a different organization's Medicaid MCO, in a prepaid ambulatory or inpatient health plan (PAHP or PIHP), or through a state's Medicaid fee-for-service system. In these circumstances, the D–SNP has no control over the Medicaid grievance and appeals process. Even a D–SNP that has a Medicaid managed care organization operated by such plan's parent organization available to its enrollees, but whose members may instead enroll in other Medicaid plans, can only unify the procedures for Medicaid appeals and grievances of those enrollees who are also simultaneously enrolled in the Medicaid managed care organization controlled by such plan's parent organization. Therefore, we do not believe that it is feasible at this time to implement fully unified grievance and appeals systems for D–SNPs and Medicaid managed care plans that do not have the same enrollees or where the organizations offering the D–SNPs and Medicaid plans are unaffiliated or even competitors.

E. Accounting Statement and Table

The following table summarizes costs, savings, and transfers by provision.

As required by OMB Circular A–4 (available at *https://*

obamawhitehouse.archives.gov/omb/circulars_a004_a-4/), in Table 17, we have prepared an accounting statement showing the savings and transfers associated with the provisions of this proposed rule for calendar years 2020 through 2029. Table 17 is based on Tables 18A and B which lists savings, costs, and transfers by provision.

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TABLE 17: ACCOUNTING STATEMENT - CLASSIFICATIONS OF ESTIMATED SAVINGS, COSTS, AND TRANSFERS
Negative Numbers Indicate Savings

FROM CALENDAR YEARS 2020 TO 2024 [$ in millions]	Savings			
	Discount Rate			
	7%	3%	Period Covered	Whom is Saving, Spending or Transferring
Net Annualized Monetized Savings	2.17	2.12	CYs 2019-2029	
Annualized Monetized Savings	-----	-----	CYs 2019-2029	
Annualized Monetized Cost	2.17	2.12	CYs 2019-2029	Plans, Part D sponsors, State Agencies and the Federal Government.
Transfers	0.03	0.02	CYs 2019-2029	The State Agencies transfer 50% of their costs to the Federal Government though matching programs.

The following Table 18 summarizes savings, costs, and transfers by provision and formed a basis for the accounting table. For reasons of space, Table 18 is broken into Table 18A (2020 through 2024) and Table 18B (2025 through 2029). In these tables savings are indicated as negative numbers in columns marked savings while costs are indicated as positive numbers in columns marked costs. Transfers may be negative or positive with negative numbers indicating savings to the Medicare Trust Fund and positive numbers indicating costs to the Medicare Trust Fund. All numbers are in millions. The row ''aggregate total by year'' gives the total of costs and savings for that year but does not include transfers. Tables 18A and B form the basis for Table 16 and for the calculation to the infinite horizon discounted to 2016 and mentioned in the conclusion.

TABLE 18A: AGGREGATE SAVINGS, COSTS, AND TRANSFERS IN MILLIONS BY PROVISION AND YEAR FROM 2020 TO 2024

	2020 Savings	2020 Cost	2020 Transfers	2021 Savings	2021 Cost	2021 Transfers	2022 Savings	2022 Cost	2022 Transfers	2023 Savings	2023 cost	2023 Transfers	2024 Savings	2024 Cost	2024 Transfers
Total Savings	0.0			0.0			0.0			0.0			0.0		
Total Costs		4.9			1.7			1.7			1.7			1.7	
Aggregate Total	4.9			1.7			1.7			1.7			1.7		
Total Transfers			0.2			0.0			0.0			0.0			0.0
D-SNP Integration		3.2	0.2												
D-SNP Grievance & Appeals					0.2			0.2			0.2			0.2	
Claims Data		1.7			1.5			1.5			1.5			1.5	
Star Ratings				0.0			0.0			0.0			0.0		
Preclusion				0.0			0.0			0.0			0.0		
RADV	0.0			0.0			0.0			0.0			0.0		

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TABLE 18B: AGGREGATE SAVINGS, COSTS, AND TRANSFERS IN MILLIONS BY PROVISION AND YEAR FROM 2025 TO 2029

	2025 Savings	2025 Cost	2025 Transfers	2026 Savings	2026 Cost	2026 Transfers	2027 Savings	2027 Cost	2027 Transfers	2028 Savings	2028 Cost	2028 Transfers	2029 Savings	2029 Cost	2029 Transfers
Total Savings	0.0			0.0			0.0			0.0			0.0		
Total Costs		1.8			1.8			1.8			1.8			1.9	
Aggregate Total	1.8			1.8			1.8			1.8			1.9		
Total Transfers			0.0			0.0			0.0			0.0			0.0
D-SNP Integration															
D-SNP Grievance & Appeals		0.3			0.3			0.3			0.3			0.4	
Claims Data		1.5			1.5			1.5			1.5			1.5	
Star Ratings	0.0			0.0			0.0								
Preclusion	0.0			0.0			0.0			0.0			0.0		
RADV	0.0			0.0			0.0			0.0			0.0		

F. Conclusion

As indicated in Table 17, we estimate that this proposed rule generates net annualized cost of approximately $2 million per year over 2020 through 2029. As discussed in the narrative of this Regulatory Impact Section, the Medicare Trust Fund is expected, over the next 10 years, to have an aggregate reduction in dollars spent of $4.5 billion arising from recovery of incorrect payments to plans.

G. Reducing Regulation and Controlling Regulatory Costs

The Department believes that this proposed rule, if finalized, is considered a deregulatory action under Executive Order 13771. The Department estimates that this rule generates $1.5 million in annualized costs at a 7-percent discount rate, discounted relative to 2016, over a perpetualtime horizon.

List of Subjects

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

42 CFR Part 438

Grant programs—health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 498

Administrative practice and procedure, Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend CFR chapter IV as set forth below:

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 1. The authority citation for part 422 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 422.2 is amended—

■ a. By adding definitions of ''Aligned enrollment'' and ''Dual eligible special needs plan'' in alphabetical order;

■ b. By revising the definition of ''Fully integrated dual eligible special needs plan'';

■ c. By adding the definition of ''Highly integrated dual eligible special needs plan'' in alphabetical order; and

■ d. In the definition of ''Preclusion list'' by revising the introductory text and paragraphs (1)(i), (2)(i), (2)(ii)(C) and adding paragraph (3).

The additions and revisions read as follows:

§ 422.2 Definitions.

* * * * *

Aligned enrollment refers to the enrollment in a dual eligible special needs plan of full-benefit dual eligible individuals whose Medicaid benefits are covered by such plan or by a Medicaid managed care organization, as defined in section 1903(m) of the Act, that is the same organization, its parent organization, or another entity that is owned and controlled by its parent organization. When State policy limits a dual eligible special needs plan's membership to individuals with aligned enrollment, this condition is referred to as exclusively aligned enrollment.

* * * * *

Dual eligible special needs plan or D–SNP means a specialized MA plan for special needs individuals who are entitled to medical assistance under a State plan under XIX of the Act that provides, as applicable, and coordinates the delivery of Medicare and Medicaid services, including long-term services and supports and behavioral health services, for individuals who are eligible for such services. Such a plan must have a contract with the State Medicaid agency consistent with § 422.107 that meets the minimum requirements in § 422.107(c); and, beginning January 1, 2021, must satisfy one or more of the following criteria for the integration of Medicare and Medicaid benefits:

(1) Meets the additional requirement specified in § 422.107(d) in its contract with the State Medicaid agency;

(2) Is a highly integrated dual eligible special needs plan; or

(3) Is a fully integrated dual eligible special needs plan.

* * * * *

Fully integrated dual eligible special needs plan means a dual eligible special needs plan—

(1) That provides dual eligible individuals access to Medicare and Medicaid benefits under a single entity that holds both an MA contract with CMS and a Medicaid managed care organization contract under section 1903(m) of the Act with the applicable State;

(2) Whose capitated contract with the State Medicaid agency includes coverage of specified primary care, acute care, behavioral health, and long-term services and supports, consistent with State policy, and provides coverage of nursing facility services for a period of at least 180 days during the plan year;

(3) That coordinates the delivery of covered Medicare and Medicaid services using aligned care management and specialty care network methods for high-risk beneficiaries; and

(4) That employs policies and procedures approved by CMS and the State to coordinate or integrate beneficiary communication materials, enrollment, communications, grievance and appeals, and quality improvement.

* * * * *

Highly integrated dual eligible special needs plan means a dual eligible special needs plan offered by an MA organization that also has, or whose parent organization or another entity that is owned and controlled by its parent organization has, a capitated contract with the Medicaid agency in the State in which the dual eligible special needs plan operates that includes coverage of long-term services and supports, behavioral health services, or both, consistent with State policy.

* * * * *

Preclusion list means a CMS compiled list of individuals and entities that—

(1) * * *

(i) The individual or entity is currently revoked from Medicare for a reason other than that stated in § 424.535(a)(3) of this chapter.

* * * * *

(2) * * *

(i) The individual or entity has engaged in behavior, other than that described in § 424.535(a)(3) of this chapter, for which CMS could have revoked the individual or entity to the extent applicable had they been enrolled in Medicare.

(ii) * * *

(C) Any other evidence that CMS deems relevant to its determination; or

(3) The individual or entity, regardless of whether they are or were enrolled in Medicare, has been convicted of a felony under federal or state law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program. Factors that CMS considers in making such a determination under this paragraph (3) are:

(i) The severity of the offense;

(ii) When the offense occurred; and

(iii) Any other information that CMS deems relevant to its determination.

* * * * *

■ 3. Section 422.60 is amended by revising paragraph (g)(2)(i) to read as follows:

§ 422.60 Election process.

* * * * *

(g) * * *

(2) * * *

(i) Operate as a fully integrated dual eligible special needs plan or highly integrated dual eligible special needs plan.

* * * * *

■ 4. Section 422.100 is amended by revising paragraphs (a) and (c)(1) to read as follows:

§ 422.100 General requirements.

(a) *Basic rule.* Subject to the conditions and limitations set forth in this subpart, an MA organization offering an MA plan must provide enrollees in that plan with coverage of the basic benefits described in paragraph (c)(1) of this section (except that additional telehealth benefits may be, but are not required to be, offered by the MA plan) and, to the extent applicable, supplemental benefits as described in paragraph (c)(2) of this section, by furnishing the benefits directly or through arrangements, or by paying for the benefits. CMS reviews these benefits subject to the requirements of this section and the requirements in subpart G of this part.

* * * * *

(c) * * *

(1) Basic benefits are all items and services (other than hospice care or coverage for organ acquisitions for kidney transplants) for which benefits are available under parts A and B of Medicare, including additional telehealth benefits offered consistent with the requirements at § 422.135.

* * * * *

■ 5. Section 422.102 is amended by revising paragraph (e) introductory text to read as follows:

§ 422.102 Supplemental benefits.

* * * * *

(e) *Supplemental benefits for certain dual eligible special needs plans.* Subject to CMS approval, fully integrated dual eligible special needs plans and highly integrated dual eligible special needs plans that meet minimum performance and quality-based standards may offer additional supplemental benefits, consistent with the requirements of this part, where CMS finds that the offering of such benefits could better integrate care for the dual eligible population provided that the special needs plan—

* * * * *

■ 6. Section 422.107 is amended by—

■ a. Revising the section heading;

■ b. In paragraph (a) by removing the term ''dual-eligible'' and adding in its place the term ''dual eligible'';

■ c. By revising paragraphs (b) and (c)(1), (2), and (3);

■ d. By redesignating paragraph (d) as paragraph (e);

■ e. By adding a new paragraph (d); and

■ f. By adding paragraph (e)(2).

The revisions and additions read as follows:

§ 422.107 Special needs plans and dual eligibles: Contract with State Medicaid Agency.

* * * * *

(b) *General rule.* MA organizations seeking to offer a dual eligible special needs plan must have a contract consistent with this section with the State Medicaid agency.

(c) * * *

(1) The MA organization's responsibility to provide, as applicable, and coordinate the delivery of Medicaid benefits, including long-term services and supports and behavioral health services, for individuals who are eligible for such services.

(2) The category(ies) and criteria for eligibility for dual eligible individuals to be enrolled under the SNP, including as described in the Act at sections 1902(a), 1902(f), 1902(p), and 1905.

(3) The Medicaid benefits covered by the MA organization offering the SNP under a capitated contract with the State Medicaid agency or covered for the SNP's enrollees under a risk contract as defined in § 438.2 of this chapter with a Medicaid managed care organization, as defined in section 1903(m) of the Act, offered by the SNP's parent organization or another entity that is owned and controlled by its parent organization.

* * * * *

(d) *Additional minimum contract requirement.* For any dual eligible special needs plan that is not a fully integrated or highly integrated dual eligible special needs plan, the contract must also stipulate that, for the purpose of coordinating Medicare and Medicaid-covered services between settings of care, the SNP will notify or authorize another entity or entities to notify the State Medicaid agency and/or individuals or entities designated by the State Medicaid agency of hospital and skilled nursing facility admissions for at least one group of high-risk full-benefit dual eligible individuals, identified by the State Medicaid agency. The State Medicaid agency must establish the timeframe(s) and method(s) by which notice is provided. In the event that a SNP authorizes another entity or entities to perform this notification, the SNP must retain responsibility for complying with this requirement.

(e) * * *

(2) MA organizations offering a dual eligible SNP must comply with paragraph (d) of this section beginning January 1, 2021.

* * * * *

■ 7. Section 422.111 is amended by revising paragraph (b)(2)(iii) to read as follows:

§ 422.111 Disclosure requirements.

* * * * *

(b) * * *

(2) * * *

(iii) By a dual eligible special needs plan, prior to enrollment, for each prospective enrollee, a comprehensive written statement describing cost sharing protections and benefits that the individual is entitled to under title XVIII and the State Medicaid program under title XIX.

* * * * *

■ 8. Section 422.135 is added to subpart C to read as follows:

§ 422.135 Additional telehealth benefits.

(a) *Definitions.* For purposes of this section, the following definitions apply:

Additional telehealth benefits means services that meet the following:

(1) Are furnished by an MA plan for which benefits are available under Medicare Part B but which are not payable under section 1834(m) of the Act; and

(2) Have been identified by the MA plan for the applicable year as clinically appropriate to furnish through electronic exchange.

Electronic exchange means electronic information and telecommunications technology.

(b) *General rule.* An MA plan may treat additional telehealth benefits as basic benefits covered under the original Medicare fee-for-service program for purposes of this part 422 provided that the requirements of this section are met. If the MA plan fails to comply with the requirements of this section, then the MA plan may not treat the benefits provided through electronic exchange as additional telehealth benefits, but may treat them as supplemental benefits as described in § 422.102, subject to CMS approval.

(c) *Requirements.* An MA plan furnishing additional telehealth benefits must:

(1) Furnish in-person access to the specified Part B service(s) at the election of the enrollee.

(2) Advise each enrollee, at a minimum in the MA plan's Evidence of Coverage required at § 422.111(b), that

the enrollee may receive the specified Part B service(s) through an in-person visit or through electronic exchange.

(3) Identify, in the MA plan's provider directory required at § 422.111(b)(3)(i), any providers offering services for additional telehealth benefits and in-person visits or offering services exclusively for additional telehealth benefits.

(4) Comply with the provider selection and credentialing requirements provided in § 422.204, and, when providing additional telehealth benefits, ensure through its contract with the provider that the provider meet and comply with applicable state licensing requirements and other applicable laws for the state in which the enrollee is located and receiving the service.

(5) Make information about coverage of additional telehealth benefits available to CMS upon request. Information may include, but is not limited to, statistics on use or cost, manner(s) or method of electronic exchange, evaluations of effectiveness, and demonstration of compliance with the requirements of this section.

(d) *Requirement to use contracted providers.* An MA plan furnishing additional telehealth benefits may only do so using contracted providers. Coverage of benefits furnished by a non-contracted provider through electronic exchange may only be covered as a supplemental benefit.

(e) *Bidding.* An MA plan that fully complies with this section may include additional telehealth benefits in its bid for basic benefits in accordance with § 422.254.

(f) *Cost sharing.* MA plans offering additional telehealth benefits may maintain different cost sharing for the specified Part B service(s) furnished through an in-person visit and the specified Part B service(s) furnished through electronic exchange.

§ 422.156 [Amended]

■ 9. Section 422.156 is amended in paragraph (b)(1) by removing the phrase ''the quality improvement projects (QIPs) and''.

■ 10. Section 422.162 is amended in paragraph (a) by adding the definitions of ''Absolute percentage cap'', ''Cut point cap'', ''Guardrail'', ''Mean resampling'', ''Restricted range'', and ''Restricted range cap'' in alphabetical order to read as follows:

§ 422.162 Medicare Advantage Quality Rating System.

(a) * * *

Absolute percentage cap is a cap applied to non-CAHPS measures that are on a 0 to 100 scale that restricts movement of the current year's measure-threshold-specific cut point to no more than the stated percentage as compared to the prior year's cut point.

* * * * *

Cut point cap is a restriction on the change in the amount of movement a measure-threshold-specific cut point can make as compared to the prior year's measure-threshold-specific cut point. A cut point cap can restrict upward movement, downward movement, or both.

* * * * *

Guardrail is a bidirectional cap that restricts both upward and downward movement of a measure-threshold-specific cut point for the current year's measure-level Star Ratings as compared to the prior year's measure-threshold-specific cut point.

* * * * *

Mean resampling refers to a technique where measure-specific scores for the current year's Star Ratings are randomly separated into 10 equal-sized groups. The hierarchal clustering algorithm is done 10 times, each time leaving one of the 10 groups out. The method results in 10 sets of measure-specific cut points. The mean cut point for each threshold per measure is calculated using the 10 values.

* * * * *

Restricted range is the difference between the maximum and minimum measure score values using the prior year measure scores excluding outer fence outliers (first quartile − 3*Interquartile Range (IQR) and third quartile + 3*IQR).

Restricted range cap is a cap applied to non-CAHPS measures that restricts movement of the current year's measure-threshold-specific cut point to no more than the stated percentage of the restricted range of a measure calculated using the prior year's measure score distribution.

* * * * *

■ 11. Section 422.164 is amended by adding paragraphs (f)(1)(v), (g)(1)(iii)(O), and (h) to read as follows:

§ 422.164 Adding, updating, and removing measures.

* * * * *

(f) * * *

(1) * * *

(v) CMS will exclude any measure that receives a measure-level Star Rating reduction for data integrity concerns for either the current or prior year from the improvement measure(s).

* * * * *

(g) * * *

(1) * * *

(iii) * * *

(O) CMS will reduce a measure rating to 1 star for the applicable appeals measure(s) if a contract fails to submit Timeliness Monitoring Project data for CMS's review to ensure the completeness of the contract's IRE data.

* * * * *

(h) *Review of sponsors' data.* (1) A request for CMS or the IRE to review a contract's appeals data must be received no later than June 30 of the following year.

(2) A request for CMS to review a contract's Complaints Tracking Module (CTM) data must be received no later than June 30 of the following year.

■ 12. Section 422.166 is amended by revising paragraph (a)(2)(i) and adding paragraph (i) to read as follows:

§ 422.166 Calculation of Star Ratings.

(a) * * *

(2) * * *

(i) The method maximizes differences across the star categories and minimizes the differences within star categories using mean resampling with the hierarchal clustering of the current year's data, and a guardrail so that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the value of the cap from one year to the next. The cap is equal to 5 percentage points for measures having a 0 to 100 scale (absolute percentage cap) or 5 percent of the restricted range for measures not having a 0 to 100 scale (restricted range cap). New measures that have been in the Part C and D Star Rating program for three years or less use the hierarchal clustering methodology with mean resampling with no guardrail for the first three years in the program.

* * * * *

(i) *Extreme and uncontrollable circumstances.* In the event of extreme and uncontrollable circumstances that may negatively impact operational and clinical systems and contracts' abilities to conduct surveys needed for accurate performance measurement, CMS will calculate the Star Ratings as specified in paragraphs (i)(2) through (10) of this section for each contract that is an affected contract during the performance period for the applicable measures.

(1) *Identification of affected contracts.* A contract that meets all of the following criteria is an affected contract:

(i) The contract's service area is within an ''emergency area'' during an ''emergency period'' as defined in section 1135(g) of the Act.

(ii) The contract's service area is within a county, parish, U.S. territory or

tribal area designated in a major disaster declaration under the Stafford Act and the Secretary exercised authority under section 1135 of the Act based on the same triggering event(s).

(iii) As specified in paragraphs (i)(2) through (10) of this section, a certain minimum percentage (25 percent or 60 percent) of the enrollees under the contract must reside in a Federal Emergency Management Agency (FEMA)-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance.

(2) *CAHPS adjustments.* (i) A contract, even if an affected contract, must administer the CAHPS survey unless exempt under paragraph (i)(2)(ii) of this section.

(ii) An affected contract will be exempt from administering the CAHPS survey if the contract completes both of the following:

(A) Demonstrates to CMS that the required sample for the survey cannot be contacted because a substantial number of the contract's enrollees are displaced due to the FEMA-designated disaster identified in paragraph (i)(1)(iii) of this section in the prior calendar year.

(B) Requests and receives a CMS approved exception.

(iii) An affected contract with an exception defined in paragraph (i)(2)(ii) of this section will receive the contract's CAHPS measure stars and corresponding measure scores from the prior year.

(iv) For an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance, the contract will receive the higher of the previous year's Star Rating or the current year's Star Rating (and corresponding measure score) for each CAHPS measure.

(3) *HOS adjustments.* (i) An affected contract must administer the HOS survey unless exempt under paragraph (i)(3)(ii) of this section.

(ii) An affected contract will be exempt from administering the HOS survey if the contract completes the following:

(A) Demonstrates to CMS that the required sample for the survey cannot be contacted because a substantial number of the contract's enrollees are displaced due to the FEMA-designated disaster identified in (i)(1)(iii) of this section during the measurement period.

(B) Requests and receives a CMS approved exception.

(iii) Affected contracts with an exception defined in paragraph (i)(3)(ii) of this section will receive the prior year's HOS and Healthcare Effectiveness Data and Information Set (HEDIS)-HOS measure stars and corresponding measure scores.

(iv) For an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance, the affected contract will receive the higher of the previous year's Star Rating or the current year's Star Rating (and corresponding measure score) for each HOS and HEDIS–HOS measure.

(4) *HEDIS adjustments.* (i) An affected contract must report HEDIS data unless exempted under paragraph (i)(4)(ii) of this section.

(ii) An affected contract will be exempt from reporting HEDIS data if the contract completes the following:

(A) Demonstrates an inability to obtain both administrative and medical record data that are required for reporting HEDIS measures due to a FEMA-designated disaster in the prior calendar year.

(B) Requests and receives a CMS approved exception.

(iii) Affected contracts with an exception defined in paragraph (i)(4)(ii) of this section will receive the prior year's HEDIS measure stars and corresponding measure scores.

(iv) Affected contracts that do not have an exception defined in paragraph (i)(4)(ii) of this section may contact National Committee for Quality Assurance (NCQA) to request modifications to the samples for measures that require medical record review.

(v) For an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance, the affected contract will receive the higher of the previous year's Star Rating or the current year's Star Rating (and corresponding measure score) for each HEDIS measure.

(5) *New measure adjustments.* For affected contracts with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance, CMS will apply a hold harmless provision by comparing the result of the contract's summary and/or overall rating with and without including all of the applicable new measures. If the ''with'' result is lower than the ''without'' result, then CMS will use the ''without'' result as the final rating.

(6) *Other Star Ratings measure adjustments.* (i) For all other measures except those measures identified in this paragraph (i)(6)(ii) of this section, affected contracts with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance will receive the higher of the previous or current year's measure Star Rating and then use the corresponding measure score.

(ii) CMS will not adjust the scores or Star Ratings for the following measures, unless the exception in paragraph (i)(6)(iii) of this section applies.

(A) Part C Call Center—Foreign Language Interpreter and TTY Availability.

(B) Part D Call Center—Foreign Language Interpreter and TTY Availability.

(iii) CMS will adjust the measures listed in paragraph (i)(6)(ii) of this section using the adjustments listed in paragraph (i)(6)(i) of this section for contracts affected by extreme and uncontrollable circumstances where there are continuing communications issues related to loss of electricity and damage to infrastructure during the call center study.

(7) *Exclusion from improvement measures.* Any measure that reverts back to the data underlying the previous year's Star Rating due to the adjustments made in paragraph (i) of this section will be excluded from both the count of measures and the applicable improvement measures for the current and next year's Star Ratings for the affected contract.

(8) *Missing data.* For an affected contract that has missing data in the current or previous year, the final measure rating will come from the current year unless any of the exceptions described in paragraphs (i)(2)(ii), (i)(3)(ii), and (i)(4)(ii) of this section apply.

(9) *Cut points for non-CAHPS measures.* (i) CMS will exclude the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the clustering algorithms described in paragraph (a)(2) of this section.

(ii) The cut points calculated as described in paragraph (i)(9)(i) of this section will be used to assess all affected contracts' measure Star Ratings.

(10) *Reward Factor.* (i) CMS will exclude the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the determination of

the performance summary and variance thresholds for the Reward Factor described in paragraph (f)(1) of this section.

(ii) All affected contracts will be eligible for the Reward Factor based on the calculations described in paragraph (i)(10)(i) of this section.

■ 13. Section 422.222 is amended by revising paragraph (a) to read as follows:

§ 422.222 Preclusion list.

(a)(1)(i) Except as provided in paragraph (a)(1)(ii) of this section, an MA organization must not make payment for a health care item or service furnished by an individual or entity that is included on the preclusion list, defined in § 422.2.

(ii) With respect to MA providers that have been added to an updated preclusion list, the MA organization must do all of the following:

(A) No later than 30 days after the posting of this updated preclusion list, must provide an advance written notice to any beneficiary who has received an MA service or item from the individual or entity added to the preclusion list in this update;

(B) Must ensure that reasonable efforts are made to notify the individual or entity described in paragraph (a)(1)(ii) of this section of a beneficiary who was sent a notice under paragraph (a)(1)(ii)(A) of this section; and

(C) Must not deny payment for a service or item furnished by the newly added individual or entity, solely on the ground that they have been included in the updated preclusion list, in the 60-day period after the date it sent the notice described in paragraph (a)(1)(ii)(A) of this section.

(2)(i) CMS sends written notice to the individual or entity via letter of their inclusion on the preclusion list. The notice must contain the reason for the inclusion and inform the individual or entity of their appeal rights. An individual or entity may appeal their inclusion on the preclusion list, defined in § 422.2, in accordance with part 498 of this chapter.

(ii) If the individual's or entity's inclusion on the preclusion list is based on a contemporaneous Medicare revocation under § 424.535 of this chapter:

(A) The notice described in paragraph (a)(2)(i) of this section must also include notice of the revocation, the reason(s) for the revocation, and a description of the individual's or entity's appeal rights concerning the revocation.

(B) The appeals of the individual's or entity's inclusion on the preclusion list and the individual's or entity's revocation shall be filed jointly by the individual or entity and, as applicable, considered jointly by CMS under part 498 of this chapter.

(3)(i) Except as provided in paragraph (a)(3)(ii) of this section, an individual or entity will only be included on the preclusion list after the expiration of either of the following:

(A) If the individual or entity does not file a reconsideration request under § 498.5(n)(1) of this chapter, the individual or entity will be added to the preclusion list upon the expiration of the 60-day period in which the individual or entity may request a reconsideration; or

(B) If the individual or entity files a reconsideration request under § 498.5(n)(1) of this chapter, the individual or entity will be added to the preclusion list effective on the date on which CMS, if applicable, denies the individual's or entity's reconsideration.

(ii) An OIG excluded individual or entity is added to the preclusion list effective on the date of the exclusion.

(4) Payment denials based upon an individual's or entity's inclusion on the preclusion list are not appealable by beneficiaries.

(5)(i) Except as provided in paragraphs (a)(5)(iii) and (iv) of this section, an individual or entity that is revoked under § 424.535 of this chapter will be included on the preclusion list for the same length of time as the individual's or entity's reenrollment bar.

(ii) Except as provided in paragraphs (a)(5)(iii) and (iv) of this section, an individual or entity that is not enrolled in Medicare will be included on the preclusion list for the same length of time as the reenrollment bar that CMS could have imposed on the individual or entity had they been enrolled and then revoked.

(iii) Except as provided in paragraph (a)(5)(iv) of this section, an individual or entity, regardless of whether they are or were enrolled in Medicare, that is included on the preclusion list because of a felony conviction will remain on the preclusion list for a 10-year period, beginning on the date of the felony conviction, unless CMS determines that a shorter length of time is warranted. Factors that CMS considers in making such a determination are:

(A) The severity of the offense.

(B) When the offense occurred.

(C) Any other information that CMS deems relevant to its determination.

(iv) In cases where an individual or entity is excluded by the OIG, the individual or entity shall remain on the preclusion list until the expiration of the CMS-imposed preclusion list period or reinstatement by the OIG, whichever occurs later.

* * * * *

■ 14. Section 422.252 is amended by revising the definition of ''MA monthly basic beneficiary premium'', ''MA monthly MSA premium'', ''Monthly aggregate bid amount'', ''Plan basic cost sharing'', and ''Unadjusted MA statutory non-drug monthly bid amount'' to read as follows:

§ 422.252 Terminology.

* * * * *

MA monthly basic beneficiary premium means the premium amount (if any) an MA plan (except an MSA plan) charges an enrollee for basic benefits as defined in § 422.100(c)(1), and is calculated as described at § 422.262.

MA monthly MSA premium means the amount of the plan premium for coverage of basic benefits as defined in § 422.100(c)(1) through an MSA plan, as set forth at § 422.254(e).

* * * * *

Monthly aggregate bid amount means the total monthly plan bid amount for coverage of an MA eligible beneficiary with a nationally average risk profile for the factors described in § 422.308(c), and this amount is comprised of the following:

(1) The unadjusted MA statutory non-drug monthly bid amount for coverage of basic benefits as defined in § 422.100(c)(1);

(2) The amount for coverage of basic prescription drug benefits under Part D (if any); and

(3) The amount for provision of supplemental health care benefits (if any).

* * * * *

Plan basic cost sharing means cost sharing that would be charged by a plan for basic benefits as defined in § 422.100(c)(1) before any reductions resulting from mandatory supplemental benefits.

* * * * *

Unadjusted MA statutory non-drug monthly bid amount means a plan's estimate of its average monthly required revenue to provide coverage of basic benefits as defined in § 422.100(c)(1) to an MA eligible beneficiary with a nationally average risk profile for the risk factors CMS applies to payment calculations as set forth at § 422.308(c).

■ 15. Section 422.254 is amended by—

■ a. Revising paragraph (b)(1)(i);

■ b. Adding paragraph (b)(3)(i);

■ c. Reserving paragraph (b)(3)(ii); and

■ d. Revising paragraphs (b)(4), (c)(3)(i), and (e)(2).

The revisions and addition read as follows:

§ 422.254 Submission of bids.

* * * * *

(b) * * *

(1) * * *

(i) The unadjusted MA statutory non-drug monthly bid amount, which is the MA plan's estimated average monthly required revenue for providing basic benefits as defined in § 422.100(c)(1).

* * * * *

(3) * * *

(i) MA plans offering additional telehealth benefits as defined in § 422.135(a) must exclude any capital and infrastructure costs and investments relating to such benefits from their bid submission.

(ii) [Reserved]

(4) The bid amount is for plan payments only but must be based on plan assumptions about the amount of revenue required from enrollee cost-sharing. The estimate of plan cost-sharing for the unadjusted MA statutory non-drug monthly bid amount for coverage of basic benefits as defined in § 422.100(c)(1) must reflect the requirement that the level of cost sharing MA plans charge to enrollees must be actuarially equivalent to the level of cost sharing (deductible, copayments, or coinsurance) charged to beneficiaries under the original Medicare fee-for-service program option. The actuarially equivalent level of cost sharing reflected in a regional plan's unadjusted MA statutory non-drug monthly bid amount does not include cost sharing for out-of-network Medicare benefits, as described at § 422.101(d).

* * * * *

(c) * * *

(3) * * *

(i) The provision of basic benefits as defined in § 422.100(c)(1);

* * * * *

(e) * * *

(2) The amount of the MA monthly MSA premium for basic benefits (as defined in § 422.252);

* * * * *

■ 16. Section 422.264 is amended by revising paragraph (a) to read as follows:

§ 422.264 Calculation of savings.

(a) *Computation of risk adjusted bids and benchmarks*—(1) *The risk adjusted MA statutory non-drug monthly bid amount* is the unadjusted MA statutory non-drug monthly bid amount (defined at § 422.254(b)(1)(i)), adjusted using the factors described in paragraph (c) of this section for local plans and paragraph (e) of this section for regional plans.

(2) The *risk adjusted MA area-specific non-drug monthly benchmark amount* is the unadjusted benchmark amount for coverage of basic benefits defined in § 422.100(c)(1) by a local MA plan, adjusted using the factors described in paragraph (c) of this section.

(3) The *risk adjusted MA region-specific non-drug monthly benchmark amount* is the unadjusted benchmark amount for coverage of basic benefits defined in § 422.100(c)(1) by a regional MA plan, adjusted using the factors described in paragraph (e) of this section.

* * * * *

■ 17. Section 422.300 is revised to read as follows:

§ 422.300 Basis and scope.

This subpart is based on 42 U.S.C. 1106, 1128j(d), 1852, 1853, 1854, and 1858. It sets forth the rules for making payments to MA organizations offering local and regional MA policies, including calculation of MA capitation rates and benchmarks, conditions under which payment is based on plan bids, adjustments to capitation rates (including risk adjustment), collection of risk adjustment data, conditions for use and disclosure of risk adjustment data, collection of improper payments and other payment rules. See § 422.458 for rules on risk sharing payments to MA regional organizations.

■ 18. Section 422.310 is amended by revising paragraph (e) to read as follows:

§ 422.310 Risk adjustment data.

* * * * *

(e) *Validation of risk adjustment data.* MA organizations and their providers and practitioners will be required to submit a sample of medical records for the validation of risk adjustment data, as required by CMS. There may be penalties for submission of false data. MA organizations must remit improper payments based on RADV audits and established in accordance with stated methodology, in a manner specified by CMS. For RADV audits, CMS may extrapolate RADV Contract-Level audit findings to Payment Year 2011 forward.

* * * * *

■ 19. Section 422.311 is amended by revising paragraph (a) to read as follows:

§ 422.311 RADV audit dispute and appeal processes.

(a) *Risk adjustment data validation (RADV) audits.* In accordance with §§ 422.2 and 422.310(e), the Secretary annually conducts RADV audits to ensure risk adjusted payment integrity and accuracy. Recovery of improper payments from MA organizations will be conducted according to the Secretary's payment error extrapolation and recovery methodologies. CMS will apply extrapolation to plan year audits for payment year 2011 forward.

* * * * *

■ 20. Section 422.504 is amended by adding paragraph (g)(1)(iv) to read as follows:

§ 422.504 Contract provisions.

* * * * *

(g) * * *

(1) * * *

(iv) The enrollee shall not have any financial liability for services or items furnished to the enrollee by an MA contracted individual or entity on the preclusion list, as defined in § 422.2 and as described in § 422.222.

* * * * *

■ 21. Section 422.560 is amended by adding paragraphs (a)(4) and (b)(5) to read as follows:

§ 422.560 Basis and scope.

(a) * * *

(4) Section 1859(f)(8) of the Act provides for, to the extent feasible, unifying grievances and appeals procedures under sections 1852(f), 1852(g), 1902(a)(3), 1902(a)(5), and 1932(b)(4) of the Act for Medicare and Medicaid covered items and services provided by specialized MA plans for special needs individuals described in subsection 1859(b)(6)(B)(ii) of the Act for individuals who are eligible under titles XVIII and XIX. Procedures established under section 1859(f)(8) of the Act apply in place of otherwise applicable grievances and appeals procedures with respect to Medicare and Medicaid covered items and services provided by applicable integrated plans.

(b) * * *

(5) Requirements for applicable integrated plans with respect to procedures for integrated grievances, integrated organization determinations, and integrated reconsiderations.

* * * * *

■ 22. Section 422.561 is amended by adding definitions of ''Applicable integrated plans'', ''Integrated appeal'', ''Integrated grievance'', ''Integrated organization determination'', and ''Integrated reconsideration'' in alphabetical order to read as follows:

§ 422.561 Definitions.

* * * * *

Applicable integrated plan means:

(1) A fully integrated dual eligible special needs plan with exclusively aligned enrollment or a highly integrated dual eligible special needs plan with exclusively aligned enrollment, and

(2) The Medicaid managed care organization, as defined in section

1903(m) of the Act, through which such dual eligible special needs plan, its parent organization, or another entity that is owned and controlled by its parent organization covers Medicaid services for dually eligible individuals enrolled in such dual eligible special needs plan and such Medicaid managed care organization.

* * * * *

Integrated appeal means any of the procedures that deal with, or result from, adverse integrated organization determinations by an applicable integrated plan on the health care services the enrollee believes he or she is entitled to receive, including delay in providing, arranging for, or approving the health care services (such that a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for a service. Integrated appeals cover procedures that would otherwise be defined and covered, for non-applicable integrated plans, as an appeal defined in § 422.561 or the procedures required for appeals pursuant to §§ 438.400 through 438.424 of this chapter. Such procedures include integrated reconsiderations.

Integrated grievance means a dispute or compliant that would be defined and covered, for grievances filed by an enrollee in non-applicable integrated plans, under § 422.564 or §§ 438.400 through 438.416 of this chapter. Integrated grievances do not include appeals procedures and QIO complaints, as described in § 422.564(b) and (c). An integrated grievance made by an enrollee in an applicable integrated plan is subject to the integrated grievance procedures in §§ 422.629 and 422.630.

Integrated organization determination means an organization determination that would otherwise be defined and covered, for a non-applicable integrated plan, as organizational determinations under § 422.566 and an adverse benefit determination under § 438.400(b) and § 431.201 (definition of action) of this chapter. An integrated organization determination is made by an applicable integrated plan and is subject to the integrated organization determination procedures in §§ 422.629, 422.631, and 422.634.

Integrated reconsideration means a reconsideration that would otherwise be defined and covered, for a non-applicable integrated plan, as a reconsideration under § 422.580 and appeal under § 438.400(b) of this chapter. An integrated reconsideration is made by an applicable integrated plan and is subject to the integrated reconsideration procedures in §§ 422.629 and 422.632 through 422.634.

* * * * *

■ 23. Section 422.562 is amended by—
■ a. Revising paragraph (a)(1)(i);
■ b. By adding paragraph (a)(5); and
■ c. By revising paragraph (b).

The revisions and addition read as follows:

§ 422.562 General provisions.

(a) * * *

(1) * * *

(i) A grievance procedure as described in § 422.564 or § 422.630 as applicable, for addressing issues that do not involve organization determinations;

* * * * *

(5) An MA organization that offers a dual eligible special needs plan has the following additional responsibilities—

(i) The dual eligible special needs plan must offer to assist an enrollee in that dual eligible special needs plan with obtaining Medicaid covered services and resolving grievances, including requesting authorization of Medicaid services, as applicable, and navigating Medicaid appeals and grievances in connection with the enrollee's own Medicaid coverage, regardless of whether such coverage is in Medicaid fee-for-service or a Medicaid managed care plan, such as a Medicaid MCO, PIHP, or PAHP as defined in § 438.2 of this chapter. If the enrollee accepts the offer of assistance, the plan must provide the assistance. Examples of such assistance include:

(A) Explaining to an enrollee how to make a request for Medicaid authorization of a service and how to file appeal following an adverse benefit determination, such as:

(*1*) Assisting the enrollee in identifying the enrollee's specific Medicaid managed care plan or fee-for-service point of contact;

(*2*) Providing specific instructions for contacting the appropriate agency in a fee-for-service setting or for contacting the enrollee's Medicaid managed care plan, regardless of whether the Medicaid managed care plan is affiliated with the enrollee's dual eligible special needs plan; and

(*3*) Assisting the enrollee in making contact with the enrollee's fee-for-service contact or Medicaid managed care plan.

(B) Assisting a beneficiary in filing a Medicaid grievance or a Medicaid appeal.

(C) Assisting an enrollee in obtaining documentation to support a request for authorization of Medicaid services or a Medicaid appeal.

(ii) The dual eligible special needs plan must offer to provide the assistance described in paragraph (a)(5)(i) of this section whenever it becomes aware of an enrollee's need for a Medicaid-covered service. Offering such assistance is not dependent on an enrollee's specific request.

(iii) The dual eligible special needs plan must offer to provide and actually provide assistance as required by paragraph (a)(5)(i) of this section using multiple methods.

(A) When an enrollee accepts the offer of assistance described in paragraph (a)(5)(i) of this section, the dual eligible special needs plan may coach the enrollee on how to self-advocate.

(B) The dual eligible special needs plan must also provide an enrollee reasonable assistance in completing forms and taking procedural steps related to grievances and appeals, including when assisting with Medicaid appeals.

(iv) The dual eligible special needs plan must, upon request from CMS, provide documentation demonstrating its compliance with this paragraph (a)(5).

(v) The obligation to provide assistance under paragraph (a)(5)(i) of this section does not create an obligation for a dual eligible special needs plan to represent an enrollee in a Medicaid appeal.

(b) *Rights of MA enrollees.* In accordance with the provisions of this subpart, enrollees have the following rights:

(1) The right to have grievances between the enrollee and the MA organization heard and resolved, as described in §§ 422.564 or 422.630, as applicable.

(2) The right to a timely organization determination, as provided under §§ 422.566 or 422.631, as applicable.

(3) The right to request an expedited organization determination, as provided under §§ 422.570 or 422.631(e), as applicable.

(4) If dissatisfied with any part of an organization determination, the following appeal rights:

(i) The right to a reconsideration of the adverse organization determination by the MA organization, as provided under §§ 422.578 or 422.633, as applicable.

(ii) The right to request an expedited reconsideration, as provided under §§ 422.584 or 422.633(f), as applicable.

(iii) If, as a result of a reconsideration, an MA organization affirms, in whole or in part, its adverse organization determination, the right to an automatic reconsidered determination made by an independent, outside entity contracted by CMS, as provided in § 422.592.

* * * * *

■ 24. Section 422.566 is amended by revising paragraph (a) to read as follows:

§ 422.566 Organization determinations.

(a) *Responsibilities of the MA organization.* Each MA organization must have a procedure for making timely organization determinations (in accordance with the requirements of this subpart) regarding the benefits an enrollee is entitled to receive under an MA plan, including basic benefits as described under § 422.100(c)(1) and mandatory and optional supplemental benefits as described under § 422.102, and the amount, if any, that the enrollee is required to pay for a health service. The MA organization must have a standard procedure for making determinations, in accordance with § 422.568, and an expedited procedure for situations in which applying the standard procedure could seriously jeopardize the enrollee's life, health, or ability to regain maximum function, in accordance with §§ 422.570 and 422.572; for an applicable integrated plan, the MA organization must comply with §§ 422.629 through 422.634 in lieu of §§ 422.566(c) and (d), 422.568, 422.570 and 422.572 with regard to the procedures for making determinations, including integrated organization determinations and integrated reconsiderations, on a standard and expedited basis.

* * * * *

■ 25. Section 422.629, 422.630, 422.631, 422.632, 422.633, and 422.634 are added to Subpart M under the center heading, ''Requirements Applicable to Certain Integrated Dual Eligible Special Needs Plans'' to read as follows:

Subpart M—Grievances, Organization Determinations and Appeals

* * * * *

Requirements Applicable to Certain Integrated Dual Eligible Special Needs Plans

Sec.

422.629 General requirements for applicable integrated plans.
422.630 Integrated grievances.
422.631 Integrated organization determinations.
422.632 Continuation of benefits while the applicable integrated plan reconsideration is pending.
422.633 Integrated reconsideration.
422.634 Effect.

Requirements Applicable to Certain Integrated Dual Eligible Special Needs Plans

§ 422.629 General requirements for applicable integrated plans.

(a) *Scope.* The provisions in this section and in §§ 422.630 through 422.634 set forth requirements for unified appeals and grievance processes with which applicable integrated plans must comply.

(1) These provisions apply to an applicable integrated plan in lieu of §§ 422.564, 422.566(c) and (d), and 422.568 through 422.590 and §§ 438.404 through 438.424 of this chapter.

(b) *General process.* An applicable integrated plan must create integrated processes for enrollees for integrated grievances and for integrated organization determinations, and for integrated reconsiderations.

(c) *State flexibilities.* A State may, at its discretion, implement standards for timeframes or notice requirements that are more protective for the enrollee than required by this section and §§ 422.630 through 422.634. The contract under § 422.107 must include any standards that differ from the standards set forth in this section.

(d) *Evidence.* The applicable integrated plan must provide the enrollee a reasonable opportunity, in person and in writing, to present evidence and testimony and make legal and factual arguments for integrated grievances, integrated reconsiderations. The applicable integrated plan must inform the enrollee of the limited time available for presenting evidence sufficiently in advance of the resolution timeframe for appeals as specified in this section if the case is being considered under an expedited timeframe for the integrated grievance or integrated reconsideration.

(e) *Assistance.* In addition to the requirements in § 422.562(a)(5), the applicable integrated plan must provide an enrollee reasonable assistance in completing forms and taking other procedural steps related to integrated grievances and integrated appeals.

(f) *Applicable requirements.* The requirements in §§ 422.560, 422.561, 422.562, 422.566, and 422.592 through 422.626 apply to an applicable integrated plan unless otherwise provided in this section or in §§ 422.630 through 422.634.

(g) *Acknowledgement.* The applicable integrated plan must send to the enrollee written acknowledgement of integrated grievances and integrated reconsiderations upon receiving the request.

(h) *Recordkeeping.* (1) The applicable integrated plan must maintain records of integrated grievances and integrated appeals. Each applicable integrated plan that is a Medicaid managed care organization must review the Medicaid-related information as part of its ongoing monitoring procedures, as well as for updates and revisions to the State quality strategy.

(2) The record of each integrated grievance or integrated appeal must contain, at a minimum:

(i) A general description of the reason for the integrated appeal or integrated grievance.

(ii) The date of receipt.

(iii) The date of each review or, if applicable, review meeting.

(iv) Resolution at each level of the integrated appeal or integrated grievance, if applicable.

(v) Date of resolution at each level, if applicable.

(vi) Name of the enrollee for whom the integrated appeal or integrated grievance was filed.

(vii) Date the applicable integrated plan notified the enrollee of the resolution.

(3) The record of each integrated grievance or integrated appeal must be accurately maintained in a manner accessible to the State and available upon request to CMS.

(i) *Prohibition on punitive action.* Each applicable integrated plan must ensure that no punitive action is taken against a provider that requests an integrated organization determination or integrated reconsideration, or supports an enrollee's request for these actions.

(j) *Information to providers and subcontractors.* The applicable integrated plan must provide information about the integrated grievance and integrated appeal system to all providers and subcontractors at the time they enter into a contract including, at minimum, information on integrated grievance, integrated reconsideration, and fair hearing procedures and timeframes as applicable. Such information must include:

(1) The right to file an integrated grievance and integrated reconsideration.

(2) The requirements and timeframes for filing an integrated grievance or integrated reconsideration.

(3) The availability of assistance in the filing process.

(k) *Review decision-making requirement*—(1) *General rules.* Individuals making decisions on integrated appeals and grievances must take into account all comments, documents, records, and other

information submitted by the enrollee or their representative without regard to whether such information was submitted or considered in the initial adverse integrated organization determination.

(2) *Integrated grievances.* Individuals making decisions on integrated grievances must be individuals who:

(i) Were neither involved in any previous level of review or decision-making nor a subordinate of any such individual.

(ii) If deciding any of the following, have the appropriate clinical expertise in treating the enrollee's condition or disease:

(A) A grievance regarding denial of expedited resolution of an appeal.

(B) A grievance that involves clinical issues.

(3) *Integrated organization determinations.* If the applicable integrated plan expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the integrated organization determination must be reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare and Medicaid coverage criteria, before the applicable integrated plan issues the integrated organization determination. Any physician or other health care professional who reviews an integrated organization determination must have a current and unrestricted license to practice within the scope of his or her profession.

(4) *Integrated reconsideration determinations.* Individuals making an integrated reconsideration determination must be individuals who:

(i) Were neither involved in any previous level of review or decision-making nor a subordinate of any such individual.

(ii) If deciding an appeal of a denial that is based on lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), are a physician or other appropriate health care professional who have the appropriate clinical expertise, in treating the enrollee's condition or disease, and knowledge of Medicare coverage criteria, before the MA organization issues the organization determination decision.

(l) *Parties.* (1) The individuals or entity who can request an integrated grievance and integrated organization determination and integrated reconsideration are:

(i) The enrollee or his or her representative;

(ii) An assignee of the enrollee (that is, a physician or other provider who has furnished or intends to furnish a service to the enrollee and formally agrees to waive any right to payment from the enrollee for that service), or any other provider or entity (other than the applicable integrated plan) who has an appealable interest in the proceeding. If the provider is requesting an integrated reconsideration on behalf of an enrollee, the provider must provide notice to the enrollee. If the provider or authorized representative requests that the benefits continue while the appeal is pending, pursuant to § 422.632 and consistent with state law, the provider or authorized representative must obtain the written consent of the enrollee to request the appeal on behalf of the enrollee; or

(iii) The legal representative of a deceased enrollee's estate.

(2) When the term ''enrollee'' is used throughout this section, it includes providers that file a request and authorized representatives consistent with this paragraph, unless otherwise specified.

(3) The parties who can request an expedited integrated organization determination are—

(i) The enrollee (including his or her representative); or

(ii) A provider.

§ 422.630 Integrated grievances.

(a) *General rule.* In lieu of complying with § 422.564, and the grievance requirements of §§ 438.402, 438.406, 438.408, 438.414, and 438.416 of this chapter, each applicable integrated plan must comply with this section. Each applicable integrated plan must provide meaningful procedures for timely hearing and resolving integrated grievances between enrollees and the applicable integrated plan or any other entity or individual through which the applicable integrated plan provides health care services.

(b) *Timing.* An enrollee may file an integrated grievance at any time with the applicable integrated plan.

(c) *Filing.* An enrollee may file an integrated grievance orally or in writing with the applicable integrated plan, or with the State for an integrated grievance related to a Medicaid benefit, if the State has a process for accepting Medicaid grievances.

(d) *Expedited grievances.* An applicable integrated plan must respond to an enrollee's grievance within 24 hours if:

(1) The complaint involves the applicable integrated plan's decision to invoke an extension relating to an integrated organization determination or integrated reconsideration.

(2) The complaint involves the applicable integrated plan's refusal to grant an enrollee's request for an expedited organization determination under § 422.631 or integrated reconsideration under § 422.633.

(e) *Resolution and notice.* (1) The applicable integrated plan must resolve standard integrated grievances as expeditiously as the case requires, based on the enrollee's health status, but no later than 30 calendar days from the date it receives the integrated grievance.

(i) All integrated grievances submitted in writing must be responded to in writing.

(ii) Integrated grievances submitted orally may be responded to either orally or in writing, unless the enrollee requests a written response.

(iii) All integrated grievances related to quality of care, regardless of how the integrated grievance is filed, must be responded to in writing. The response must include a description of the enrollee's right to file a written complaint with the QIO with regard to Medicare covered services. For any complaint submitted to a QIO, the applicable integrated plan must cooperate with the QIO in resolving the complaint.

(2) The timeframe for resolving the integrated grievance may be extended by 14 calendar days if the enrollee requests an extension or if the applicable integrated plan justifies the need for additional information and documents how the delay is in the interest of the enrollee. When the applicable integrated plan extends the timeframe, it must:

(i) Make reasonable efforts to promptly notify the enrollee orally of the reasons for the delay, and

(ii) Send written notice to the enrollee of the reasons for the delay immediately, but no later than within 2 calendar days. This notice must explain the right to file an integrated grievance if the enrollee disagrees with the decision to delay.

§ 422.631 Integrated organization determinations.

(a) *General rule.* An applicable integrated plan must adopt and implement a process for enrollees to request that the plan make an integrated organization determination. The process for requesting that the applicable integrated plan make an integrated organization determination must be the same for all covered benefits.

(b) *Requests.* The enrollee, or a provider on behalf of an enrollee, may request an integrated organization determination orally or in writing, except for requests for payment, which must be in writing (unless the applicable integrated plan or entity responsible for making the determination has implemented a voluntary policy of accepting verbal payment requests).

(c) *Expedited integrated organization determinations.* (1) An enrollee, or a provider on behalf of an enrollee, may request an expedited integrated organization determination.

(2) The request can be oral or in writing.

(3) The applicable integrated plan must complete an expedited integrated organization determination when the applicable integrated plan determines (based on a request from the enrollee or on its own) or the provider indicates (in making the request on the enrollee's behalf or supporting the enrollee's request) that taking the time for a standard resolution could seriously jeopardize the enrollee's life, physical or mental health, or ability to attain, maintain, or regain maximum function.

(d) *Timeframes and notice*—(1) *Integrated organization determination notice.* The applicable integrated plan must send an enrollee a written notice of any adverse decision on an integrated organization determination (including a determination to authorize a service or item in an amount, duration, or scope that is less than the amount previously requested or authorized for an ongoing course of treatment) within the timeframes set forth in this section. For an integrated organization determination not reached within the timeframes specified in this section (which constitutes a denial and is thus an adverse decision), the applicable integrated plan must send a notice on the date that the timeframes expire. Such notice must describe all applicable Medicare and Medicaid appeal rights. Integrated organization determination notices must be written in plain language, be available in a language and format that is accessible to the enrollee, and explain:

(i) The applicable integrated plan's determination;

(ii) The date the determination was made;

(iii) The date the determination will take effect;

(iv) The reasons for the determination;

(v) The enrollee's right to file an integrated reconsideration and the ability for someone else to file an appeal on the enrollee's behalf;

(vi) Procedures for exercising enrollee's rights to an integrated reconsideration;

(vii) Circumstances under which expedited resolution is available and how to request it; and

(viii) If applicable, the enrollee's rights to have benefits continue pending the resolution of the integrated appeal process.

(2) *Timing of notice*—(i) *Standard integrated organization determinations.* (A) The applicable integrated plan must send a notice of its integrated organization determination at least 10 days before the date of action (that is, before the date on which a termination, suspension, or reduction becomes effective), in cases where a previously approved service is being reduced, suspended, or terminated, except in circumstances where an exception is permitted under §§ 431.213 and 431.214 of this chapter.

(B) For other integrated organization determinations that are not expedited integrated organization determinations, the applicable integrated plan must send a notice of its integrated organization determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days from when it receives the request for the integrated organization determination.

(ii) *Extensions.* The applicable integrated plan may extend the timeframe for a standard or expedited integrated organization determination by up to 14 calendar days if:

(A) The enrollee or provider requests the extension; or

(B) The applicable integrated plan can show that:

(*1*) The extension is in the enrollee's interest; and

(*2*) There is need for additional information and there is a reasonable likelihood that receipt of such information would lead to approval of the request, if received.

(iii) *Notices in cases of extension.* (A) When the applicable integrated plan extends the timeframe, it must notify the enrollee in writing of the reasons for the delay as expeditiously as the enrollee's health condition requires but no later than upon expiration of the extension, and inform the enrollee of the right to file an expedited integrated grievance if he or she disagrees with the applicable integrated plan's decision to grant an extension.

(B) If the applicable integrated plan extends the timeframe for making its integrated organization determination, it must send the notice of its determination as expeditiously as the enrollee's health condition requires and no later than the date the extension expires.

(iv) *Expedited integrated organization determinations.* (A) The applicable integrated plan must provide notice of its expedited integrated organization determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request.

(B) If the applicable integrated plan denies the request for an expedited integrated organization determination, it must:

(*1*) Automatically transfer a request to the standard timeframe and make the determination within the 14-day timeframe established in this paragraph for a standard integrated organization determination. The 14-day period begins with the day the applicable integrated plan receives the request for expedited integrated organization determination.

(*2*) Give the enrollee prompt oral notice of the denial and transfer and subsequently deliver, within 3 calendar days, a written letter that—

(*i*) Explains that the applicable integrated plan will process the request using the 14-day timeframe for standard integrated organization determinations;

(*ii*) Informs the enrollee of the right to file an expedited integrated grievance if he or she disagrees with the applicable integrated plan's decision not to expedite;

(*iii*) Informs the enrollee of the right to resubmit a request for an expedited integrated organization determination with any physician's support; and

(*iv*) Provides instructions about the integrated grievance process and its timeframes.

(C) If the applicable integrated plan must receive medical information from noncontract providers, the applicable integrated plan must request the necessary information from the noncontract provider within 24 hours of the initial request for an expedited integrated organization determination. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the applicable integrated plan in meeting the required timeframe. Regardless of whether the applicable integrated plan must request information from noncontract providers, the applicable integrated plan is responsible for meeting the timeframe and notice requirements of this section.

§ 422.632 Continuation of benefits while the applicable integrated plan reconsideration is pending.

(a) *Definition.* As used in this section, timely files means files for continuation of benefits on or before the later of the following:

(1) Within 10 calendar days of the applicable integrated plan sending the notice of adverse integrated organization determination.

(2) The intended effective date of the applicable integrated plan's proposed adverse integrated organization determination.

(b) *Continuation of benefits.* The applicable integrated plan must continue the enrollee's benefits under Parts A and B of title XVIII and title XIX if all of the following occur:

(1) The enrollee files the request for an integrated appeal timely in accordance with § 422.633(e);

(2) The integrated appeal involves the termination, suspension, or reduction of previously authorized services;

(3) The services were ordered by an authorized provider;

(4) The period covered by the original authorization has not expired; and

(5) The enrollee timely files for continuation of benefits.

(c) *Duration of continued or reinstated benefits.* If, at the enrollee's request, the applicable integrated plan continues or reinstates the enrollee's benefits, as described in paragraph (b) of this section, while the integrated reconsideration is pending, the benefits must be continued until:

(1) The enrollee withdraws the request for an integrated reconsideration;

(2) The applicable integrated plan issues an integrated reconsideration that is unfavorable to the enrollee related to the benefit that has been continued;

(3) For an appeal involving Medicaid benefits:

(i) The enrollee fails to file a request for a State fair hearing and continuation of benefits, within 10 calendar days after the applicable integrated plan sends the notice of the integrated reconsideration;

(ii) The enrollee withdraws the appeal or request for a State fair hearing;

(iii) A State fair hearing office issues a hearing decision adverse to the enrollee.

(d) *Recovery of costs.* In the event the appeal or State fair hearing is adverse to the enrollee, the applicable integrated plan or State agency may not pursue recovery for services provided, to the extent that the services were furnished solely under of the requirements of this section.

§ 422.633 Integrated reconsideration.

(a) *General rule.* An applicable integrated plan may only have one level of integrated reconsideration for an enrollee.

(b) *External medical reviews.* If a State has established an external medical review process, the requirements of § 438.402(c)(1)(i)(B) of this chapter apply to each applicable integrated plan that is a Medicaid managed care organization, as defined in section 1903 of the Act.

(c) *Case file.* Upon request of the enrollee or his or her representative, the applicable integrated plan must provide the enrollee and his or her representative the enrollee's case file, including medical records, other documents and records, and any new or additional evidence considered, relied upon, or generated by the applicable integrated plan (or at the direction of the applicable integrated plan) in connection with the appeal of the integrated organization determination. This information must be provided free of charge and sufficiently in advance of the resolution timeframe for appeals as specified in this section.

(d) *Timing.* (1) An enrollee has 60 calendar days from the date on the adverse organization determination notice to file a request for an integrated reconsideration with the applicable integrated plan.

(2) Oral inquires seeking to appeal an adverse integrated organization determination must be treated as a request for an integrated reconsideration (to establish the earliest possible filing date for the appeal).

(3) *Extending the time for filing a request*—(i) *General rule.* If a party or physician acting on behalf of an enrollee shows good cause, the applicable integrated plan may extend the timeframe for filing a request for an integrated reconsideration.

(ii) *How to request an extension of timeframe.* If the 60-day period in which to file a request for an integrated reconsideration has expired, a party to the integrated organization determination or a physician acting on behalf of an enrollee may file a request for integrated reconsideration with the applicable integrated plan. The request for integrated reconsideration and to extend the timeframe must—

(A) Be in writing; and

(B) State why the request for integrated reconsideration was not filed on time.

(e) *Expedited integrated reconsiderations.* (1) An enrollee may request, or a provider may request on behalf of an enrollee, an expedited review of the integrated reconsideration.

(2) The request can be oral or in writing.

(3) The applicable integrated plan must grant the request to expedite the integrated reconsideration when it determines (for a request from the enrollee), or the provider indicates (in making the request on the enrollee's behalf or supporting the enrollee's request), that taking the time for a standard resolution could seriously jeopardize the enrollee's life, physical or mental health, or ability to attain, maintain, or regain maximum function.

(4) If an applicable integrated plan denies an enrollee's request for an expedited integrated reconsideration, it must automatically transfer a request to the standard timeframe and make the determination within the 30-day timeframe established in paragraph (f)(1) of this section for a standard integrated reconsideration. The 30-day period begins with the day the applicable integrated plan receives the request for expedited integrated reconsideration. The applicable integrated plan must give the enrollee prompt oral notice of the decision, and give the enrollee written notice within 2 calendar days. The written notice must:

(i) Include the reason for the denial;

(ii) Inform the enrollee of the right to file a grievance if the enrollee disagrees with the decision not to expedite, including timeframes and procedures for filing a grievance; and

(iii) Inform the enrollee of the right to resubmit a request for an expedited determination with any physician's support.

(5) If the applicable integrated plan must receive medical information from noncontract providers, the applicable integrated plan must request the necessary information from the noncontract provider within 24 hours of the initial request for an expedited integrated reconsideration. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the applicable integrated plan in meeting the required timeframe. Regardless of whether the applicable integrated plan must request information from noncontract providers, the applicable integrated plan is responsible for meeting the timeframe and notice requirements of this section.

(f) *Resolution and notification.* The applicable integrated plan must make integrated reconsidered determinations as expeditiously as the enrollee's health condition requires but no later than the timeframes established in this section.

(1) *Standard integrated reconsiderations.* The applicable

integrated plan must resolve integrated reconsiderations within 30 calendar days of receipt of the request or as expeditiously as the enrollee's health condition requires for the integrated reconsideration. This timeframe may be extended as described in paragraph (f)(3) of this section.

(2) *Expedited integrated reconsiderations.* The applicable integrated plan must resolve expedited integrated reconsiderations within 72 hours of receipt of the request or as expeditiously as the enrollee's health condition requires for the integrated reconsideration. This timeframe may be extended as described in paragraph (f)(3) of this section. The applicable integrated plan must make reasonable efforts to provide prompt oral notice of the expedited resolution to the enrollee.

(3) *Extensions.* (i) The applicable integrated plan may extend the timeframe for resolving integrated reconsiderations by 14 calendar days if:

(A) The enrollee requests the extension; or

(B) The applicable integrated plan can show that:

(*1*) The extension is in the enrollee's interest; and

(*2*) There is need for additional information and there is a reasonable likelihood that receipt of such information would lead to approval of the request, if received.

(ii) If the applicable integrated plan extends the timeframe for resolving the integrated reconsideration, it must make reasonable efforts to give the enrollee prompt oral notice of the delay, and give the enrollee written notice within 2 calendar days. The notice must include the reason for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the decision to grant an extension.

(4) *Notice of resolution.* The applicable integrated plan must send a notice to enrollees that includes the integrated reconsidered determination, within the resolution timeframes set forth in this section. The notice of determination must be written in plain language and available in a language and format that is accessible to the enrollee, and must explain:

(i) The resolution of and basis for the integrated reconsideration and the date it was completed.

(ii) For integrated reconsiderations not resolved wholly in favor of the enrollee:

(A) An explanation of the next level of appeal available under the Medicare and Medicaid programs, and what steps the enrollee must take to pursue the next level of appeal under each program; and

(B) The right to request and receive Medicaid-covered benefits while the next level of appeal is pending, if applicable.

§ 422.634 Effect.

(a) *Failure of the applicable integrated plan to send timely notice of a determination.* If the applicable integrated plan fails to adhere to the notice and timing for an integrated organization determination or integrated reconsideration, this failure constitutes an adverse determination for the enrollee. For an integrated organization determination, this means that the enrollee may request an integrated reconsideration (to the next applicable level in the appeal process). For integrated reconsiderations of Medicare benefits, this means the applicable integrated plan must forward the case to the independent review entity, in accordance with the timeframes under paragraph (b) of this section and § 422.592. For integrated reconsiderations of Medicaid benefits, this means that an enrollee or other party may file for a State fair hearing, or if applicable, a State external medical review in accordance with § 438.402(c) of this chapter.

(b) *Adverse integrated reconsiderations.* (1) Subject to paragraph (b)(2) of this section, when the applicable integrated plan affirms, in whole or in part, its adverse integrated organization determination involving a Medicare benefit:

(i) The issues that remain in dispute must be reviewed and resolved by an independent, outside entity that contracts with CMS, in accordance with § 422.592 and §§ 422.594 through 422.619; and

(ii) For standard integrated reconsiderations, the applicable integrated plan must prepare a written explanation and send the case file to the independent review entity contracted by CMS, as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request (or no later than the expiration of an extension described in § 422.633(f)(3)). The applicable integrated plan must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(iii) For expedited integrated reconsiderations, the applicable integrated plan must prepare a written explanation and send the case file to the independent review entity contracted by CMS as expeditiously as the enrollee's health condition requires, but no later than within 24 hours of its affirmation (or no later than the expiration of an extension described in § 422.633(f)(3)). The applicable integrated plan must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(2) When the applicable integrated plan affirms, in whole or in part, its adverse integrated organization determination involving a Medicaid benefit, the enrollee or other party (that is not the applicable integrated plan) may initiate a State fair hearing no later than 120 calendar days from the date of the applicable integrated plan's notice of resolution. If a provider is filing for a State fair hearing on behalf of the enrollee as permitted by State law, the provider will need the written consent of the enrollee, if he or she has not already obtained such consent.

(c) *Final determination.* The reconsidered determination of the applicable integrated plan is binding on all parties unless it is appealed to the next applicable level. In the event that the enrollee pursues the appeal in multiple forums and receives conflicting decisions, the applicable integrated plan is bound by, and must act in accordance with, decisions favorable to the enrollee.

(d) *Services not furnished while the appeal is pending.* If an applicable integrated plan, or a State fair hearing with regard to a Medicaid benefit, reverses a decision to deny, limit, or delay services that were not furnished while the appeal was pending, the applicable integrated plan must authorize or provide the disputed services promptly and as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination. Reversals by the Part C independent review entity, an administrative law judge or attorney adjudicator at the Office of Medicare Hearings and Appeals, or the Medicare Appeals Council must be effectuated under same timelines applicable to other MA plans as specified in §§ 422.618 and 422.619.

(e) *Services furnished while the appeal is pending.* If the applicable integrated plan or the State fair hearing officer reverses a decision to deny, limit, or delay Medicaid-covered benefits, and the enrollee received the disputed services while the integrated reconsideration was pending, the applicable integrated plan or the State must pay for those services, in accordance with State policy and regulations. If the applicable integrated plan reverses a decision to deny, limit, or delay Medicare-covered benefits, and the enrollee received the disputed services while the integrated reconsideration was pending, the

applicable integrated plan must pay for those services.

■ 26. Section 422.752 is amended by adding paragraph (d) to read as follows:

§ 422.752 Basis for imposing intermediate sanctions and civil money penalties.

* * * * *

(d) *Special rule for non-compliant dual eligible special needs plans.* Notwithstanding any other provision of this section, CMS must impose during plan years 2021 through 2025 intermediate sanctions specified at § 422.750(a) on an MA organization with a contract to operate a dual eligible special needs plan if CMS determines that the dual eligible special needs plan fails to comply with at least one of the criteria for the integration of Medicare and Medicaid benefits provided in the definition of a dual eligible special needs plan at § 422.2. If CMS imposes such an intermediate sanction, the MA organization must submit to CMS a corrective action plan in a form, manner, and timeframe established by CMS. The procedures outlined in § 422.756 apply to the imposition of the intermediate sanction under this provision.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 27. The authority citation for part 423 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1395w–101 through 1395w–152, and 1395hh.

■ 28. Section 423.100 is amended in the definition of ''Preclusion list'' by revising paragraphs (1)(i), (2)(i), (2)(ii)(C) and adding paragraph (3) to read as follows:

§ 423.100 Definitions.

* * * * *

Preclusion list * * *

(1) * * *

(i) The prescriber is currently revoked from Medicare for a reason other than that stated in § 424.535(a)(3) of this chapter.

* * * * *

(2) * * *

(i) The prescriber has engaged in behavior, other than that described in § 424.535(a)(3) of this chapter, for which CMS could have revoked the prescriber to the extent applicable had the prescriber been enrolled in Medicare.

* * * * *

(ii) * * *

(C) Any other evidence that CMS deems relevant to its determination; or

(3) The prescriber, regardless of whether the prescriber is or was enrolled in Medicare, has been convicted of a felony under federal or state law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program. Factors that CMS considers in making such a determination under this paragraph are:

(i) The severity of the offense;

(ii) When the offense occurred; and

(iii) Any other information that CMS deems relevant to its determination.

* * * * *

■ 29. Section 423.120 is amended by—

■ a. Revising paragraphs (c)(6)(i) through (v) and (c)(6)(vi) introductory text; and

■ b. Adding paragraphs (c)(6)(vii) and (viii).

The revisions and additions read as follows:

§ 423.120 Access to covered Part D drugs.

* * * * *

(c) * * *

(6)(i) Except as provided in paragraph (c)(6)(iv) of this section, a Part D sponsor must reject, or must require its PBM to reject, a pharmacy claim for a Part D drug if the prescriber who prescribed the drug is included on the preclusion list, defined in § 423.100.

(ii) Except as provided in paragraph (c)(6)(iv) of this section, a Part D sponsor must deny, or must require its PBM to deny, a request for reimbursement from a Medicare beneficiary if the request pertains to a Part D drug that was prescribed by a prescriber who is identified by name in the request and who is included on the preclusion list, defined in § 423.100.

(iii) A Part D plan sponsor may not submit a prescription drug event (PDE) record to CMS unless it includes on the PDE record the active and valid NPI of the prescriber of the drug, and the prescriber is not included on the preclusion list, defined in § 423.100, for the date of service.

(iv) With respect to Part D prescribers that have been added to an updated preclusion list, the Part D plan sponsor must do all of the following:

(A) Subject to all other Part D rules and plan coverage requirements, and no later than 30 days after the posting of this updated preclusion list, must provide an advance written notice to any beneficiary who has received a Part D drug prescribed by a prescriber added to the preclusion list in this update;

(B) Must ensure that reasonable efforts are made to notify the prescriber described in paragraph (c)(6)(iv) of this section of a beneficiary who was sent a notice under paragraph (c)(6)(iv)(A) of this section; and

(C) Must not reject a pharmacy claim or deny a beneficiary request for reimbursement for a Part D drug prescribed by the prescriber, solely on the ground that they have been included in the updated preclusion list, in the 60-day period after the date it sent the notice described in paragraph (c)(6)(iv)(A) of this section.

(v)(A) CMS sends written notice to the prescriber via letter of their inclusion on the preclusion list. The notice must contain the reason for the inclusion on the preclusion list and inform the prescriber of their appeal rights. A prescriber may appeal their inclusion on the preclusion list under this section in accordance with part 498 of this chapter.

(B) If the prescriber's inclusion on the preclusion list is based on a contemporaneous Medicare revocation under § 424.535 of this chapter:

(*1*) The notice described in paragraph (c)(6)(v)(A) of this section must also include notice of the revocation, the reason(s) for the revocation, and a description of the prescriber's appeal rights concerning the revocation.

(*2*) The appeals of the prescriber's inclusion on the preclusion list and the prescriber's revocation shall be filed jointly by the prescriber and, as applicable, considered jointly by CMS under part 498 of this chapter.

(C)(*1*) Except as provided in paragraph (c)(6)(v)(C)(*2*) of this section, a prescriber will only be included on the preclusion list after the expiration of either of the following:

(*i*) If the prescriber does not file a reconsideration request under § 498.5(n)(1) of this chapter, the prescriber will be added to the preclusion list upon the expiration of the 60-day period in which the prescriber may request a reconsideration.

(ii) If the prescriber files a reconsideration request under § 498.5(n)(1) of this chapter, the prescriber will be added to the preclusion list effective on the date on which CMS, if applicable, denies the prescriber's reconsideration.

(2) An OIG excluded prescriber is added to the preclusion list effective on the date of the exclusion.

(vi) CMS has the discretion not to include a particular prescriber on (or, if warranted, remove the prescriber from) the preclusion list should it determine that exceptional circumstances exist regarding beneficiary access to prescriptions. In making a determination as to whether such circumstances exist, CMS takes into account—

* * * * *

(vii)(A) Except as provided in paragraphs (c)(6)(vii)(C) and (D) of this

section, a prescriber who is revoked under § 424.535 of this chapter will be included on the preclusion list for the same length of time as the prescriber's reenrollment bar.

(B) Except as provided in paragraphs (c)(6)(vii)(C) and (D) of this section, a prescriber who is not enrolled in Medicare will be included on the preclusion list for the same length of time as the reenrollment bar that CMS could have imposed on the prescriber had the prescriber been enrolled and then revoked.

(C) Except as provided in paragraph (c)(6)(vii)(D) of this section, a prescriber, regardless of whether the prescriber is or was enrolled in Medicare, that is included on the preclusion list because of a felony conviction will remain on the preclusion list for a 10-year period, beginning on the date of the felony conviction, unless CMS determines that a shorter length of time is warranted. Factors that CMS considers in making such a determination are—

(*1*) The severity of the offense;

(*2*) When the offense occurred; and

(*3*) Any other information that CMS deems relevant to its determination.

(D) In cases where a prescriber is excluded by the OIG, the prescriber must remain on the preclusion list until the expiration of the CMS-imposed preclusion list period or reinstatement by the OIG, whichever occurs later.

(viii) Payment denials under paragraph (c)(6) of this section that are based upon the prescriber's inclusion on the preclusion list are not appealable by beneficiaries.

* * * * *

■ 30. Section 423.153 is amended by revising the section heading and adding paragraph (g) to read as follows:

§ 423.153 Prescription drug plan sponsors' access to Medicare Parts A and B claims data extracts.

* * * * *

(g) *Parts A and B claims data extracts*—(1) *General rule.* (i) Beginning in plan year 2020, a PDP sponsor may submit a request to CMS for the data described in paragraph (g)(2) of this section about enrollees in its prescription drug plans.

(ii) CMS will make the data requested in paragraph (g)(1)(i) of this section available to eligible PDP sponsors, in accordance with all applicable laws. The data will be provided at least quarterly on a specified release date, and in an electronic format to be determined by CMS.

(iii) If CMS determines or has a reasonable belief that the PDP sponsor has violated the requirements of this paragraph (g) or that unauthorized uses, reuses, or disclosures of the Medicare claims data have taken place, at CMS' sole discretion, the PDP sponsor may be denied further access to the data described in paragraph (g)(2) of this section.

(2) *Data described.* The data that may be requested under paragraph (g)(1) of this section are standardized extracts of claims data under Medicare parts A and B for items and services furnished under such parts to beneficiaries who are enrolled in a plan offered by the PDP sponsor at the time of the disclosure.

(3) *Purposes.* A PDP sponsor must comply with all laws that may be applicable to data received under this provision, including state and federal privacy and security laws, and, furthermore subject to the limitations in paragraph (g)(4) of this section may only use or disclose the data provided by CMS under paragraph (g)(1) of this section for the following purposes:

(i) To optimize therapeutic outcomes through improved medication use, as such phrase is used in paragraph (d)(1)(i) of this section.

(ii) To improve care coordination so as to prevent adverse health outcomes, such as preventable emergency department visits and hospital readmissions.

(iii) For activities falling under paragraph (1) of the definition of ''health care operations'' under 45 CFR 164.501.

(iv) For activities falling under paragraph (2) of the definition of ''health care operations'' under 45 CFR 164.501.

(v) For ''fraud and abuse detection or compliance activities'' under 45 CFR 164.506(c)(4)(ii).

(vi) For disclosures that qualify as ''required by law'' disclosures at 45 CFR 164.103.

(4) *Limitations.* A PDP sponsor must comply with the following requirements regarding the data provided by CMS under this paragraph (g):

(i) The PDP sponsor will not use the data to inform coverage determinations under Part D;

(ii) The PDP sponsor will not use the data to conduct retroactive reviews of medically accepted indications determinations;

(iii) The PDP sponsor will not use the data to facilitate enrollment changes to a different prescription drug plan or an MA–PD plan offered by the same parent organization;

(iv) The PDP sponsor will not use the data to inform marketing of benefits.

(v) The PDP sponsor will contractually bind its contractors that have access to the Medicare claims data, and any other potential downstream data recipients, to the terms and conditions imposed on the PDP Sponsor under this paragraph (g).

(5) *Ensuring the privacy and security of data.* As a condition of receiving the requested data, the PDP sponsor must attest that it will adhere to the permitted uses and limitations on the use of the Medicare claims data listed in paragraphs (g)(3) and (4) of this section.

■ 31. Section 423.182 is amended in paragraph (a) by adding the definitions of ''Absolute percentage cap'', ''Cut point cap'', ''Guardrail'', ''Mean resampling'', ''Restricted range'', and ''Restricted range cap'' in alphabetical order to read as follows:

§ 423.182 Part D Prescription Drug Plan Quality Rating System.

(a) * * *

Absolute percentage cap is a cap applied to non-CAHPS measures that are on a 0 to 100 scale that restricts movement of the current year's measure-threshold-specific cut point to no more than the stated percentage as compared to the prior year's cut point.

* * * * *

Cut point cap is a restriction on the change in the amount of movement a measure-threshold-specific cut point can make as compared to the prior year's measure-threshold-specific cut point. A cut point cap can restrict upward movement, downward movement, or both.

* * * * *

Guardrail is a bidirectional cap that restricts both upward and downward movement of a measure-threshold-specific cut point for the current year's measure-level Star Ratings as compared to the prior year's measure-threshold-specific cut point.

* * * * *

Mean resampling refers to a technique where measure-specific scores for the current year's Star Ratings are randomly separated into 10 equal-sized groups. The hierarchal clustering algorithm is done 10 times, each time leaving one of the 10 groups out. The method results in 10 sets of measure-specific cut points. The mean cut point for each threshold per measure is calculated using the 10 values.

* * * * *

Restricted range is the difference between the maximum and minimum measure score values using the prior year measure scores excluding outer fence outliers (first quartile − 3 * Interquartile Range (IQR) and third quartile + 3 * IQR).

Restricted range cap is a cap applied to non-CAHPS measures that restricts movement of the current year's

measure-threshold-specific cut point to no more than the stated percentage of the restricted range of a measure calculated using the prior year's measure score distribution.

* * * * *

■ 32. Section 423.184 is amended by adding paragraphs (f)(1)(iv), (g)(1)(ii)(M), and (h) to read as follows:

§ 423.184 Adding, updating, and removing measures.

* * * * *

(f) * * *

(1) * * *

(iv) CMS will exclude any measure that receives a measure-level Star Rating reduction for data integrity concerns for either the current or prior year from the improvement measure(s).

* * * * *

(g) * * *

(1) * * *

(ii) * * *

(M) CMS will reduce a measure rating to 1 star for the applicable appeals measure(s) if a contract fails to submit Timeliness Monitoring Project data for CMS's review to ensure the completeness of the contract's IRE data.

* * * * *

(h) *Review of sponsors' data.* (1) A request for CMS or the IRE to review a contract's appeals data must be received no later than June 30 of the following year.

(2) A request for CMS to review a contract's Complaints Tracking Module (CTM) data must be received no later than June 30 of the following year.

■ 33. Section 423.186 is amended by revising paragraph (a)(2)(i) and adding paragraph (i) to read as follows:

§ 423.186 Calculation of Star Ratings.

(a) * * *

(2) * * *

(i) The method maximizes differences across the star categories and minimizes the differences within star categories using mean resampling with the hierarchal clustering of the current year's data, and a guardrail so that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the value of the cap from one year to the next. The cap is equal to 5 percentage points for measures having a 0 to 100 scale (absolute percentage cap) or 5 percent of the restricted range for measures not having a 0 to 100 scale (restricted range cap). New measures that have been in the Part C and D Star Rating program for three years or less use the hierarchal clustering methodology with mean resampling with no guardrail for the first three years in the program.

* * * * *

(i) *Extreme and uncontrollable circumstances.* In the event of extreme and uncontrollable circumstances that may negatively impact operational and clinical systems and contracts' abilities to conduct surveys needed for accurate performance measurement, CMS will calculate the Star Ratings as specified in paragraphs (i)(2) through (8) of this section for each contract that is an affected contract during the performance period for the applicable measures.

(1) *Identification of affected contracts.* A contract that meets all of the following criteria is an affected contract:

(i) The contract's service area is within an ''emergency area'' during an ''emergency period'' as defined in section 1135(g) of the Act.

(ii) The contract's service area is within a county, parish, U.S. territory or tribal area designated in a major disaster declaration under the Stafford Act and the Secretary exercised authority under section 1135 of the Act based on the same triggering event(s).

(iii) As specified in paragraphs (i)(2) through (8) of this section, a certain minimum percentage (25 percent or 60 percent) of the enrollees under the contract must reside in a Federal Emergency Management Agency (FEMA)-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance.

(2) *CAHPS adjustments.* (i) A contract, even if an affected contract, must administer the CAHPS survey unless exempt under paragraph (i)(2)(ii) of this section.

(ii) An affected contract will be exempt from administering the CAHPS survey if the contract completes both of the following:

(A) Demonstrates to CMS that the required sample for the survey cannot be contacted because a substantial number of the contract's enrollees are displaced due to the FEMA-designated disaster identified in paragraph (i)(1)(iii) of this section in the prior calendar year.

(B) Requests and receives a CMS approved exception.

(iii) An affected contract with an exception defined in paragraph (i)(2)(ii) of this section will receive the contract's CAHPS measure stars and corresponding measure scores from the prior year.

(iv) For an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance, the contract will receive the higher of the previous year's Star Rating or the current year's Star Rating (and corresponding measure score) for each CAHPS measure.

(3) *New measure adjustments.* For affected contracts with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance, CMS will apply a hold harmless provision by comparing the result of the contract's summary and/or overall rating with and without including all of the applicable new measures. If the ''with'' result is lower than the ''without'' result, then CMS will use the ''without'' result as the final rating.

(4) *Other Star Ratings measure adjustments.* (i) For all other Part D measures except those measures identified in this paragraph (i)(4)(ii) of this section, affected contracts with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance will receive the higher of the previous or current year's measure Star Rating and then use the corresponding measure score.

(ii) CMS will not adjust the scores of the Star Ratings for the Part D Call Center—Foreign Language Interpreter and TTY Availability measure, unless the exception listed in paragraph (i)(4)(iii) of this section applies.

(iii) CMS will adjust the measure listed in paragraph (i)(4)(ii) of this section using the adjustments listed in paragraph (i)(4)(i) of this section for contracts affected by extreme and uncontrollable circumstances where there are continuing communications issues related to loss of electricity and damage to infrastructure during the call center study.

(5) *Exclusion from improvement measures.* Any measure that reverts back to the data underlying the previous year's Star Rating due to the adjustments made in paragraph (i) of this section will be excluded from both the count of measures and the applicable improvement measures for the current and next year's Star Ratings for the affected contract.

(6) *Missing data.* For an affected contract that has missing data in the current or previous year, the final measure rating will come from the current year unless an exception described in paragraph (i)(2)(ii) of this section applies.

(7) *Cut points for non-CAHPS measures.* (i) CMS will exclude the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable

circumstance from the clustering algorithms described in paragraph (a)(2) of this section.

(ii) The cut points calculated as described in paragraph (i)(7)(i) of this section will be used to assess all affected contracts' measure Star Ratings.

(8) *Reward factor.* (i) CMS will exclude the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the determination of the performance summary and variance thresholds for the reward factor described in paragraph (f)(1) of this section.

(ii) All affected contracts will be eligible for the reward factor based on the calculations described in paragraph (i)(8)(i) of this section.

■ 34. Section 423.568 is amended by revising paragraph (b) to read as follows:

§ 423.568 Standard timeframe and notice requirements for coverage determinations.

* * * * *

(b) *Timeframe for requests for drug benefits.* When a party makes a request for a drug benefit, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request. For an exceptions request, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the physician's or other prescriber's supporting statement or 14 calendar days after receipt of the request, whichever occurs first.

* * * * *

■ 35. Section 423.570 is amended by revising paragraph (d)(1) to read as follows:

§ 423.570 Expediting certain coverage determinations.

* * * * *

(d) * * *

(1) Make the determination within the 72-hour timeframe established in § 423.568(b) for a standard determination. The 72-hour period begins on the day the Part D plan sponsor receives the request for expedited determination. For an exceptions request, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the physician's or other prescriber's supporting statement or 14 calendar days after receipt of the request, whichever occurs first.

* * * * *

■ 36. Section 423.572 is amended by revising paragraph (a) to read as follows:

§ 423.572 Timeframes and notice requirements for expedited coverage determinations.

(a) *Timeframe for determination and notification.* Except as provided in paragraph (b) of this section, a Part D plan sponsor that approves a request for expedited determination must make its determination and notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving the request. For an exceptions request, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receipt of the physician's or other prescriber's supporting statement or 14 calendar days after receipt of the request, whichever occurs first.

* * * * *

PART 438—MANAGED CARE

■ 37. The authority for part 438 is revised to read as follows:

Authority: 42 U.S.C. 1302.

■ 38. Section 438.210 is amended by—
■ a. Revising paragraphs (c) and (d) introductory text;
■ b. Adding paragraph (d)(4); and
■ c. Revising paragraph (f).

The addition and revisions read as follows:

§ 438.210 Coverage and authorization of services.

* * * * *

(c) *Notice of adverse benefit determination.* Each contract must provide for the MCO, PIHP, or PAHP to notify the requesting provider, and give the enrollee written notice of any decision by the MCO, PIHP, or PAHP to deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than requested. For MCOs, PIHPs, and PAHPs, the enrollee's notice must meet the requirements of § 438.404. For Medicaid contracts with an applicable integrated plan, as defined in § 422.561 of this chapter, in lieu of the provisions in this paragraph governing notices of adverse benefit determinations, the provisions set forth in §§ 422.629 through 422.634 of this chapter apply to determinations affecting dually eligible individuals who are also enrolled in a dual eligible special needs plan with exclusively aligned enrollment, as defined in § 422.2 of this chapter.

(d) *Timeframe for decisions.* Each MCO, PIHP, or PAHP contract must provide for the following decisions and notices:

* * * * *

(4) For Medicaid contracts with an applicable integrated plan, as defined in § 422.561 of this chapter, timelines for decisions and notices must be compliant with the provisions set forth in in §§ 422.629 through 422.634 of this chapter in lieu of §§ 438.404 through 438.424.

* * * * *

(f) *Applicability date.* (1) Subject to paragraph (f)(2) of this section, this section applies to the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after July 1, 2017. Until that applicability date, states are required to continue to comply with § 438.210 contained in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015.

(2) Provisions in this section affecting applicable integrated plans, as defined in § 422.561 of this chapter, are applicable no later than January 1, 2021.

■ 39. Section 438.400 is amended by adding paragraph (a)(4) and revising paragraph (c) to read as follows:

§ 438.400 Statutory basis, definitions, and applicability.

(a) * * *

(4) Section 1859(f)(8)(B) of the Act requires that the Secretary, to the extent feasible, establish procedures unifying grievances and appeals procedures under sections 1852(f), 1852(g), 1902(a)(3), 1902(a)(5), and 1932(b)(4) of the Act for items and services provided, by specialized MA plans for special needs individuals described in section 1859(b)(6)(B)(ii), under Titles XVIII and XIX of the Act.

* * * * *

(c) *Applicability.* (1) Subject to paragraph (c)(2) of this section, this subpart applies to the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after July 1, 2017. Until that applicability date, states, MCOs, PIHPs, and PAHPs are required to continue to comply with subpart F contained in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015.

(2) Provisions in this section affecting applicable integrated plans, as defined

in § 422.561 of this chapter, are applicable no later than January 1, 2021.

■ 40. Section 438.402 is amended by revising paragraph (a) to read as follows:

§ 438.402 General requirements.

(a) *The grievance and appeal system.* Each MCO, PIHP, and PAHP must have a grievance and appeal system in place for enrollees. Non-emergency medical transportation PAHPs, as defined in § 438.9, are not subject to this subpart F. An applicable integrated plan as defined in § 422.561 of this chapter is not subject to this subpart F, and is instead subject to the requirements of §§ 422.629 through 422.634 of this chapter.

* * * * *

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFs/IID AND CERTAIN NFs IN THE MEDICAID PROGRAM

■ 41. The authority for part 498 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1320a–7j, and 1395hh.

■ 42. Section 498.5 is amended by revising paragraph (n)(1) to read as follows:

§ 498.5 Appeal rights.

* * * * *

(n) * * *

(1)(i) Any individual or entity that is dissatisfied with an initial determination or revised initial determination that they are to be included on the preclusion list (as defined in § 422.2 or § 423.100 of this chapter) may request a reconsideration in accordance with § 498.22(a).

(ii)(A) If the individual's or entity's inclusion on the preclusion list is based on a Medicare revocation under § 424.535 of this chapter and the individual or entity receives contemporaneous notice of both actions, the individual or entity may request a joint reconsideration of both the preclusion list inclusion and the revocation in accordance with § 498.22(a).

(B) The individual or entity may not submit separate reconsideration requests under paragraph (n)(1)(ii)(A) of this section for inclusion on the preclusion list or a revocation if the individual or entity received contemporaneous notice of both actions.

* * * * *

Dated: October 17, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 18, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2018–23599 Filed 10–26–18; 4:15 pm]

BILLING CODE 4120–01–P

FEDERAL REGISTER

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Part III

The President

Presidential Determination No. 2019–01 of October 4, 2018—Presidential Determination on Refugee Admissions for Fiscal Year 2019

Federal Register
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Presidential Documents

Title 3—

The President

Presidential Determination No. 2019–01 of October 4, 2018

Presidential Determination on Refugee Admissions for Fiscal Year 2019

Memorandum for the Secretary of State

By the authority vested in me as President by the Constitution and the laws of the United States, in accordance with section 207 of the Immigration and Nationality Act (the ''Act'') (8 U.S.C. 1157), after appropriate consultations with the Congress, and consistent with the Report on Proposed Refugee Admissions for Fiscal Year 2019 submitted to the Congress on September 17, 2018, I hereby determine and authorize as follows:

The admission of up to 30,000 refugees to the United States during Fiscal Year (FY) 2019 is justified by humanitarian concerns or is otherwise in the national interest. This number includes persons admitted to the United States during FY 2019 with Federal refugee resettlement assistance under the Amerasian immigrant admissions program, as provided below.

The admissions shall be allocated among refugees of special humanitarian concern to the United States in accordance with the following regional allocations:

Africa	11,000
East Asia	4,000
Europe and Central Asia	3,000
Latin America/Caribbean	3,000
Near East/South Asia	9,000

The number of admissions allocated to the East Asia region shall include persons admitted to the United States during FY 2019 with Federal refugee resettlement assistance under section 584 of the Foreign Operations, Export Financing, and Related Programs Appropriations Act of 1988, as contained in section 101(e) of Public Law 100–202 (Amerasian immigrants and their family members).

Additionally, you are authorized, following notification of the appropriate committees of the Congress, to transfer unused admissions allocated to a region to one or more other regions, if greater admissions are needed for such region or regions.

Consistent with section 2(b)(2) of the Migration and Refugee Assistance Act of 1962 (22 U.S.C. 2601(b)), I hereby determine that assistance to or on behalf of persons applying for admission to the United States as part of the overseas refugee admissions program will contribute to the foreign policy interests of the United States, and I accordingly designate such persons for this purpose.

Consistent with section 101(a)(42) of the Act (8 U.S.C. 1101 (a)(42)), and after appropriate consultation with the Congress, I also specify that, for FY 2019, the following persons may, if otherwise qualified, be considered refugees for the purpose of admission to the United States within their countries of nationality or habitual residence:

a. persons in Cuba

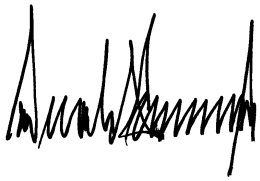
b. persons in Eurasia and the Baltics

c. persons in Iraq

d. persons in Honduras, Guatemala, and El Salvador

e. persons identified by a United States Embassy in any location, in exceptional circumstances.

You are authorized and directed to publish this determination in the *Federal Register.*



THE WHITE HOUSE,
Washington, October 4, 2018

[FR Doc. 2018–24135
Filed 10–31–18; 11:15 am]
Billing code 4710–10–P

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When a date falls on a weekend or holiday, the next Federal business day is used. (See 1 CFR 18.17)

A new table will be published in the first issue of each month.

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