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Rules and Regulations

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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.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 300

[Docket No. 190204057–9057–01]

RIN 0648–WCR–A001

Pacific Halibut Fisheries; Directed Commercial Fishery

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

ACTION: Temporary rule; inseason action.

SUMMARY: The Assistant Administrator for Fisheries, National Oceanic and Atmospheric Administration, on behalf of the International Pacific Halibut Commission, publishes notice of an inseason action pursuant to International Pacific Halibut Commission regulations approved by the Secretary of State to govern the Pacific halibut fishery. This inseason action removes the June 27, 2019, designated opening date for the Area 2A directed commercial fishery from the list of openings. This action is intended to enhance the conservation of Pacific halibut and promote safety at sea.

DATES: This action is effective May 31, 2019, through December 31, 2019.

FOR FURTHER INFORMATION CONTACT: Kathryn Blair, phone: 503–231–6858, fax: 503–231–6893, or email: *kathryn.blair@noaa.gov.*

SUPPLEMENTARY INFORMATION: The International Pacific Halibut Commission (IPHC), pursuant to the Convention between the Canada and the United States for the Preservation of the Halibut Fishery of the North Pacific Ocean and Bering Sea (Convention), signed at Ottawa, Ontario, on March 2, 1953, as amended by a Protocol Amending the Convention (signed at Washington, DC, on March 29, 1979), issued this inseason action pursuant to IPHC regulations governing the Pacific halibut fishery. The Secretary of State approved the regulations, including season dates, catch limits, and annual management measures in accordance with 50 CFR 300.62. NMFS published the regulations in the **Federal Register** on March 14, 2019 (84 FR 9243). On behalf of the IPHC, NMFS publishes the inseason action below in the **Federal Register** to provide additional notice of its effectiveness, and to inform fishery participants of the restrictions and requirements established in this inseason action.

IPHC News Release 2019–009 Non-Tribal Directed Commercial Fishery in IPHC Regulatory Area 2A: Fishing Period Limits for 26 June 2019 and 10 July 2019

Published 2 May 2019

The International Pacific Halibut Commission (IPHC) has established fishing period limits for the 26 June 2019 and 10 July 2019 fishing periods for the non-tribal directed commercial fishery (the fishery) in IPHC Regulatory Area 2A. The overall allocation for this fishery for 2019 is 254,426 pounds; 115.41 metric tons.

Note that the IPHC does not intend to establish fishing period limits for the 27 June 2019 fishing period listed in the Pacific Halibut Fishery Regulations (2019), and thus the fishery will not be open that day. The decision not to open on 27 June was informed by the response to a survey of fishery license holders conducted by the IPHC during April 2019.

The 26 June and 10 July fishing periods will each begin at 08:00 hrs and end at 18:00 hrs Pacific Daylight Time. The fishery is restricted to waters south of Point Chehalis, Washington (46°53.30′ N latitude). A total of 176 fishery licenses have been issued thus far for 2019, with 14 more applications currently being processed. Fishing period limits as indicated in the following table will be in effect for each of these two fishing periods:

Vessel class			Fishing period catch limit	
Length	Letter	Number of licenses for 2019 *	Dressed, head-on with ice/slime (pounds)	Dressed, head-on with ice/slime (metric tons)
0–25	A	16	4,525	2.05
26–30	B	11	4,525	2.05
31–35	C	18	4,525	2.05
36–40	D	36	6,820	3.09
41–45	E	29	6,820	3.09
46–50	F	31	9,090	4.12
51–55	G	10	9,090	4.12
56+	H	25	10,225	4.64

* As of 2 May 2019. Note there are 14 license applications still to be processed.

The appropriate vessel length class and letter are printed on each vessel license. The fishing period limit applies to the vessel, not the individual fisher, and any landings over the vessel limit will be subject to forfeiture and fine.

The fishing period limit is shown in terms of dressed, head-on weight, and fishers are reminded that regulations require that all Pacific halibut be landed with the head naturally attached. Additionally, fishers are reminded that there is a 72-hour rule, whereby a vessel that will be used in the fishery may not be used to fish for any species of fish anywhere in IPHC Regulatory Area 2A during the 72-hour period immediately before the non-tribal directed

commercial fishing period unless all catch of other species has been completely offloaded or the vessel has submitted to a hold inspection by an authorized officer prior to the start of the fishing period (see Pacific Halibut Fishery Regulations 2019, sections 20(7) and 20(8)).

NOAA Fisheries has implemented mandatory area closures that are in effect for the directed Pacific halibut fishery to protect specific rockfish species. For the exact coordinates of the closed areas, please refer to their web page: *http://www.westcoast.fisheries.noaa.gov/fisheries/management/groundfish_closures/groundfish_closed_areas.html.* For further information, call the NOAA Fisheries hotline at 1 800–662–9825, then press ''7'' for the Pacific halibut fisheries.

Following the 10 July 2019 fishing period, the IPHC may establish and announce fishing period limits for subsequent fishing periods in 2019, dependent upon allocation remaining for the fishery.

Dated: May 28, 2019.

Jennifer M. Wallace,

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

[FR Doc. 2019–11444 Filed 5–31–19; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 180713633–9174–02]

RIN 0648–XY001

Fisheries of the Exclusive Economic Zone Off Alaska; Yellowfin Sole 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 yellowfin sole in the Bering Sea and Aleutian Island management area (BSAI) by vessels participating in the BSAI trawl limited access sector fishery. This action is necessary to prevent exceeding the 2019 Pacific halibut prohibited species catch allowance specified for vessels participating in the BSAI trawl limited access sector yellowfin sole fishery.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), May 29, through 2400 hours, A.l.t., December 31, 2019.

FOR FURTHER INFORMATION CONTACT: Steve Whitney, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2019 Pacific halibut prohibited species catch allowance specified for vessels participating in the BSAI trawl limited access sector yellowfin sole fishery is 150 metric tons as established by the final 2019 and 2020 harvest specifications for groundfish in the BSAI (84 FR 9000, March 13, 2019).

In accordance with § 679.21(b)(4)(i)(B), the Regional Administrator finds that this prohibited species catch allowance has been reached. Consequently, NMFS is prohibiting directed fishing for yellowfin sole in the BSAI by vessels participating in the BSAI trawl limited access sector yellowfin sole fishery.

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 a 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 the yellowfin sole directed fishery in the BSAI for vessels participating in the BSAI trawl limited access sector fishery. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of May 28, 2019. 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: May 29, 2019.

Jennifer M. Wallace,

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

[FR Doc. 2019–11457 Filed 5–29–19; 4:15 pm]

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Proposed Rules

Federal Register
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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 HOMELAND SECURITY

Office of the Secretary

6 CFR Part 31

[Docket No. DHS–2008–0076]

RIN 1670–AA00

Notice of Availability of Redacted Ammonium Nitrate Security Program Technical Assessments Report

AGENCY: Cybersecurity and Infrastructure Security Agency, DHS.

ACTION: Proposed rule; notice of availability of supplemental information.

SUMMARY: The Department of Homeland Security is publishing this notice of availability in connection with the proposed rule entitled ''Ammonium Nitrate Security Program'' that was published on August 3, 2011. Through this notice, DHS is making available a redacted version of a final technical report developed by Sandia National Laboratories titled ''Ammonium Nitrate Security Program Technical Assessments.'' The report documents Sandia National Laboratories' technical research, testing, and findings related to the feasibility of weaponizing commercially available products containing ammonium nitrate. The redacted report has been added to the docket for the proposed rule. This notice solicits comments on the report and its application to the proposed definition of ammonium nitrate included as part of the Ammonium Nitrate Security Program rulemaking.

DATES: Comments are due by September 3, 2019.

ADDRESSES: You may send comments, identified by docket number and/or RIN number, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for sending comments.
- *Mail:* DHS/CISA/ISD/ISCD, ATTN: [DHS Docket No. DHS–2008–0076/RIN 1670–AA00], 245 Murray Lane SW, Mail Stop 0610, Arlington, VA 20528–0610.

Instructions: All comments received for the public docket will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Do not submit comments that include trade secrets, confidential commercial or financial information, Chemical-terrorism Vulnerability Information (CVI), Protected Critical Infrastructure Information (PCII), or Sensitive Security Information (SSI) to the public regulatory docket. Please submit comments containing protected information separately from other comments on the technical report. Comments containing this type of information should be appropriately marked as containing such information and submitted by mail to the address provided above. DHS will not place comments containing protected information in the public docket and will handle them in accordance with applicable safeguards and restrictions on access. Additionally, DHS will hold them in a separate file to which the public does not have access, and place a note in the public docket that DHS has received such protected materials from the commenter. If DHS receives a request to examine or copy this information, DHS will treat it as any other request under the Freedom of Information Act (FOIA), 5 U.S.C. 552, and the Department's FOIA regulation found in part 5 of Title 6 of the Code of Federal Regulations (CFR).

For detailed information on the types of comments sought and the types of comments that would be most useful to DHS, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read the publicly available, redacted version of Sandia National Laboratories' final technical report or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Craig Conklin, (703) 603–4805, *Craig.Conklin@hq.dhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

Section 563 of the Fiscal Year 2008 Department of Homeland Security Appropriations Act (Pub. L. 110–161, Division E (2007)), amended the Homeland Security Act of 2002, and directs DHS to ''regulate the sale and transfer of ammonium nitrate by an ammonium nitrate facility to prevent the misappropriation or use of ammonium nitrate in any act of terrorism.'' See 6 U.S.C. 488a(a). As part of this responsibility, DHS must consult with the heads of appropriate Federal departments and agencies and seek public comment in developing and implementing ammonium nitrate regulations, including establishing a threshold percentage for ammonium nitrate in a substance that will be subject to regulation. 6 U.S.C. 488a(b). The Department published an Advance Notice of Proposed Rulemaking (ANPRM) on October 29, 2008, seeking public comment on a Secure Handling of Ammonium Nitrate Program, which was followed by a Notice of Proposed Rulemaking (NPRM) for the Ammonium Nitrate Security Program for public comment on August 3, 2011. 73 FR 64280 (October 29, 2008); 76 FR 46908 (August 3, 2011). Additionally, DHS held public meetings to seek public input on the proposed rule and questions raised in the NPRM. See 76 FR 62311 (October 7, 2011); 76 FR 70366 (November 14, 2011).

In the NPRM, 76 FR 46908 (August 3, 2011), the Department proposed a definition of ammonium nitrate that included a minimum weight of 25 pounds, a minimum threshold of 30 percent ammonium nitrate by weight for mixtures, and an exemption for cold packs. The Department developed the proposed ammonium nitrate definition by considering the security benefits gained from regulating a particular transaction and the economic impact of regulating the transaction. The Department's proposal for the ammonium nitrate definition was informed by public comment received from the ANPRM; consultation with the Federal Bureau of Investigation's (FBI) Explosives Unit and a variety of other Federal, State, and private sector entities; and on a review of detonability studies available at the time the NPRM was published.

After reviewing the public input received through the notice and comment process on the proposed definition of ammonium nitrate, DHS determined that it was appropriate to seek additional scientific data on the

feasibility of weaponizing commercially available products containing ammonium nitrate before establishing a threshold percentage and quantity of ammonium nitrate that would be subject to regulation. DHS entered into an interagency agreement with the Department of Energy (DOE) on July 12, 2012 to obtain the technical expertise of Sandia National Laboratories (SNL) and to perform testing and collect data on the feasibility of weaponizing commercially available products, chemicals, and mixtures containing ammonium nitrate. The Department initiated this activity to inform both the Ammonium Nitrate Security Program rulemaking and other DHS bombing prevention and chemical security initiatives.

SNL performed a literature review to determine areas in need of technical assessments. SNL then designed technical assessments to determine the effects of total mass, physical form, and dilution on the detonability of ammonium nitrate mixtures using materials and under conditions realistic to terrorism bomb design or otherwise favorable to support detonation. SNL's technical assessments and results were reviewed on two occasions by a panel of subject matter experts, which included Federal employees from the Department of Homeland Security, the Department of Justice, the Department of Defense, the Department of State, and the Office of the Director of National Intelligence. SNL then produced a final technical report detailing the technical assessment test plans, performance, data, and a summary of the review and assessment of technical data performed by the panel.

The SNL test results showed that formulations of ammonium nitrate and pre-fabricated ammonium nitrate mixtures with various fuels would detonate with one pound of ammonium nitrate, the lowest mass tested. The results also showed that a minimum concentration level of 15% ammonium nitrate diluted with dolomite in a mixture containing a fuel detonated and that dilutions of ammonium sulfate detonated at a concentration level of 25% ammonium nitrate. When presented with the results of the testing, the panel of subject matter experts concluded that mixtures containing one pound of ammonium nitrate were detonable on the test diagnostics and that a minimum detonable level of 10% ammonium nitrate by weight could be technically defended, providing a small margin of safety beyond the 15% level, which showed a weak detonation.

The Department believes that release of SNL's final report will provide important information to those who manufacture, store, process, or engage in other transactions involving ammonium nitrate. The Department is releasing SNL's final report in a redacted format to protect information that could reasonably be expected to harm national security and/or endanger individuals' lives or physical safety because it could allow adversaries to develop effective, optimized improvised explosive devices (IEDs).

Public Participation

As noted, the SNL technical report was developed to contribute to the Department's body of knowledge on the detonability of ammonium nitrate and to inform the rulemaking process. The Department is therefore adding the report to the public docket for the proposed rule and is requesting comment from the public on the report and its potential application to the proposed definition of ammonium nitrate. The Department is specifically requesting comment on the scientific methodology and test plans SNL employed, technical data generated by SNL and test results, and factors affecting detonability thresholds. The Department would also like comment on the appropriateness of the proposed ammonium nitrate definition in light of the newly available evidence in the report, such as whether the report supports changes to the proposed mixture and weight thresholds, and the potential economic impacts of any changes to the proposed definition.

Comments that will provide the most assistance to the Department will refer to a specific section, appendix, figure, and/or table of the technical report, explain the reason for any comments, and include other information or authority that supports such comments.

This Notice is issued under the authority of 6 U.S.C. 488a.

Dated: May 28, 2019.

David Wulf,

Director, Infrastructure Security Compliance Division, Infrastructure Security Division, Cybersecurity and Infrastructure Security Agency, Department of Homeland Security.

[FR Doc. 2019–11493 Filed 5–31–19; 8:45 am]

BILLING CODE 9110–9P–P

SMALL BUSINESS ADMINISTRATION

13 CFR Part 115

[Docket No. SBA–2019–0001]

RIN 3245–AH08

Streamlining Surety Bond Guarantee Program

AGENCY: U.S. Small Business Administration.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The U.S. Small Business Administration (SBA) is soliciting comments from the public on identifying which of SBA's regulations relating to SBA's Surety Bond Guarantee Program (SBG) should be repealed, replaced, or modified because they are obsolete, unnecessary, ineffective, or burdensome. SBA is also soliciting comments from the public on how SBA can improve the surety bond products, procedures, forms, and reporting requirements of the SBG Program.

DATES: Comments must be received on or before August 2, 2019.

ADDRESSES: You may submit comments, identified by RIN 3245–AH08, docket number [SBA–2019–0001] by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jermanne Perry, Management Analyst, Office of Surety Guarantees, U.S. Small Business Administration, 409 3rd Street SW, 8th floor, Washington, DC 20416.
- *Hand Delivery/Courier:* Jermanne Perry, Management Analyst, Office of Surety Guarantees, U.S. Small Business Administration, 409 3rd Street SW, 8th floor, Washington, DC 20416.

All comments will be posted on *http://www.regulations.gov*. If you wish to submit confidential business information (CBI) as defined in the User Notice at *http://www.regulations.gov,* please submit the information to Jermanne Perry, Management Analyst, Office of Surety Guarantees, U.S. Small Business Administration, 409 3rd Street SW, 8th Floor, Washington, DC 20416, or send an email to *Jermanne.perry@sba.gov*. Highlight the information that you consider to be CBI and explain why you believe SBA should hold this information as confidential. SBA will review the information and make the final determination on whether it will publish the information.

FOR FURTHER INFORMATION CONTACT: Jermanne Perry, Management Analyst, Office of Surety Guarantees, at (202) 401–8275 or *Jermanne.perry@sba.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

The U.S. Small Business Administration (SBA) guarantees bid, payment, and performance bonds for small and emerging contractors who cannot obtain surety bonds through regular commercial channels. SBA's guarantee, authorized pursuant to Part B of Title IV of the Small Business Investment Act of 1958, 15 U.S.C. 694a *et seq.,* gives Sureties an incentive to provide bonding for small businesses and, thereby, assists small businesses in obtaining greater access to contracting opportunities. SBA's guarantee is an agreement between a Surety and SBA that SBA will assume a certain percentage of the Surety's loss should a contractor default on the underlying contract. SBA is authorized to guarantee a Surety for a contract up to $6.5 million and, with the certification of a contracting officer of a Federal agency, up to $10 million. For more information about SBA's Surety Bond Guarantee Program, see *https://www.sba.gov/funding-programs/surety-bonds.*

The regulations governing the Surety Bond Guarantee (SBG) Program are codified in 13 CFR part 115: Subpart A of part 115 contains provisions that apply to all surety bond guarantees; subpart B contains provisions that apply to the bond guarantees subject to prior approval by SBA; and subpart C contains provisions that apply to the bond guarantees that Preferred Surety Bond Sureties may issue under delegated authority. SBA is inviting comments from the public on identifying which of these regulations should be repealed, replaced, or modified because they are obsolete, unnecessary, ineffective, or burdensome. (In 2017, SBA published a similar request that covered all the agency's programs and regulations, *see* 82 FR 38618 (August 15, 2017), but SBA received no comments on part 115. By focusing only on the SBG Program, SBA believes that this request is more likely to receive the attention of interested parties.) In addition, SBA is interested in receiving comments from the public on how SBA can improve the surety bond products, procedures, forms, and reporting requirements of the SBG Program.

SBA is also considering whether to make changes to certain specific regulations and invites comments from the public on these issues. For example, SBA has received requests from Prior Approval Sureties to change the criteria in § 115.30(d)(2) for using the Quick Bond Guarantee Application and Agreement (SBA Form 990A), including increasing the maximum contract amount of $400,000, the maximum contract period of 12 months, the $1,000 per day limit on liquidated damages, and eliminating the prohibition against contracts involving demolition.

In addition, under § 115.14(a)(3), a contractor loses eligibility for future SBA assistance if the Surety has established a claim reserve of at least $1,000 for an outstanding SBA-guarantee bond. SBA is considering whether the claim reserve amount is set at the correct amount to mitigate future risk and, if not, what the amount should be. SBA is also considering whether the regulations that set the minimum amount for collecting or refunding the Principal and Surety guarantee fees, including §§ 115.32(d)(2) and (3) and 115.67(a) and (b), should be changed by increasing the amount from the current $40.

II. List of Questions for Commenters

The list of questions below is meant to assist in the formulation of public comments and is not intended to restrict the issues that may be addressed. SBA requests that commenters identify the specific regulation at issue and explain, in as much detail as possible, why the regulation should be streamlined, expanded, or repealed, including estimated cost savings and benefits to small businesses and other stakeholders.

1. Are there regulations in 13 CFR part 115 that have become unnecessary or ineffective and, if so, what are they?

2. Are there regulations in 13 CFR part 115 that can be repealed without impairing SBA's Surety Bond Guarantee Program and, if so, what are they?

3. Are there regulations in 13 CFR part 115 that have become outdated and, if so, how can they be modernized to better accomplish their regulatory objectives?

4. Are there regulations in 13 CFR part 115 that are still necessary, but which have not operated as well as expected such that a modified approach is justified, and what is that approach?

5. Are there regulations or regulatory processes in 13 CFR part 115 that are too complicated or could be streamlined to achieve regulatory objectives more efficiently?

6. Are there any technological developments that can be leveraged to modify, streamline, or repeal any existing regulatory requirements in 13 CFR part 115?

7. Should SBA make changes to any of the criteria set forth in § 115.30(d)(2) under which a Prior Approval Surety may use the Quick Bond Guarantee Application and Agreement (SBA Form 990A)? If yes, describe the change and provide the reason for your response.

8. Under § 115.14(a)(3), a contractor (and its affiliates) loses eligibility for further SBA bond guarantees if the Surety has established a claim reserve for an SBA-guaranteed bond of at least $1,000. Should SBA change the claim reserve amount? If so, describe the change and provide the reasons for your response.

9. Should SBA increase the minimum amount for collecting or refunding Principal and Surety guarantee fees from $40? If yes, what should the amount be? Please provide reasons for your response.

10. In addition to the types of bonds that are currently offered through the SBG Program, are there any other surety bond products that you would like SBA to offer through its SBG Program that would assist small businesses in need of government assistance? If so, describe the product and how it would benefit small businesses.

Interested parties are invited to provide any other comments that they may have relating to the concerns described in this advance notice of proposed rulemaking. We ask that you provide a brief justification for any suggested changes.

Authority: 15 U.S.C. 692, 694 and 695; Sec. 12079, Pub. L. 110–246, 122 Stat. 1651; E.O. 13771; E.O. 13777.

Dated: May 23, 2019.

Christopher M. Pilkerton,

Acting Administrator.

[FR Doc. 2019–11509 Filed 5–31–19; 8:45 am]

BILLING CODE 8026–03–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2019–0347; Airspace Docket No. 19–AEA–6]

RIN 2120–AA66

Proposed Establishment of Class E Airspace; Cortland, Elmira, Ithaca, and Endicott, NY

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class E airspace extending upward from 700 feet above the surface at Cortland County Airport-Chase Field, Cortland, NY, Elmira/Corning Regional Airport, Elmira/Corning, NY, Ithaca

Tompkins Regional Airport, Ithaca, NY and Tri-Cities Airport, Endicott, NY to accommodate new area navigation (RNAV) global positioning system (GPS) standard instrument approach procedures (SIAPs) serving these airports. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area.

DATES: Comments must be received on or before July 18, 2019.

ADDRESSES: Send comments on this rule to: U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Bldg., Ground Floor Rm. W12–140, Washington, DC 20590; Telephone: 1–800–647–5527, or (202) 366–9826. You must identify the Docket No. FAA–2019–0347; Airspace Docket No. 19–AEA–6, at the beginning of your comments. You may also submit and review received comments through the internet at *http://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

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

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

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337; telephone (404) 305–6364.

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 proposed rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority, as it would establish Class E airspace extending upward from 700 feet above the surface at Cortland County Airport-Chase Field, Cortland, NY, Elmira/Corning Regional Airport, Elmira/Corning, NY, Ithaca Tompkins Regional Airport, Ithaca, NY and Tri-Cities Airport, Endicott, NY to support standard instrument approach procedures for IFR operations at these airports.

Comments Invited

Interested persons are invited to comment on this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (Docket No. FAA–2019–0347 and Airspace Docket No. 19–AEA–6) and be submitted in triplicate to DOT Docket Operations (see ''**ADDRESSES**'' section for the address and phone number.) You may also submit comments through the internet at *http://www.regulations.gov.*

Persons wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2019–0347; Airspace Docket No. 19–AEA–6.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this document may be changed in light of the comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *http://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined between 8:00 a.m. and 4:30 p.m., Monday through Friday, except federal holidays at the office of the Eastern Service Center, Federal Aviation Administration, Room 350, 1701 Columbia Avenue, College Park, GA 30337.

Availability and Summary of Documents for Incorporation by Reference

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

The Proposal

The FAA is considering an amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 to establish Class E airspace extending upward from 700 feet above the surface within a 7-mile radius of Cortland County Airport-Chase Field, Cortland, NY, within a 12.5-mile radius of Elmira/Corning Regional Airport, Elmira/Corning, NY, within a 9.5-mile radius of Ithaca Tompkins Regional Airport, Ithaca, NY and within an 8-mile radius of Tri-Cities Airport, Endicott, NY, providing the controlled airspace required to support the RNAV (GPS) standard instrument approach procedures for IFR operations at these airports.

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

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal would be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

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

■ 1. The authority citation for 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 Federal Aviation Administration Order 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018, and effective September 15, 2018, is amended as follows:

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

* * * * *

AEA NY E5 Cortland, NY [New]

Cortland County Airport-Chase Field, NY
(lat. 42°35′34″ N, long. 76°12′54″ W)

That airspace extending upward from 700 feet above the surface within a 7-mile radius of Cortland County Airport-Chase Field.

* * * * *

AEA NY E5 Elmira/Corning, NY [New]

Elmira/Corning Regional Airport, NY
(lat. 42°9′35″ N, long. 76°53′30″ W)

That airspace extending upward from 700 feet above the surface within a 12.5-mile radius of Elmira/Corning Regional Airport.

* * * * *

AEA NY E5 Ithaca, NY [New]

Ithaca Tompkins Regional Airport, NY
(lat. 42°29′29″ N, long. 76°27′31″ W)

That airspace extending upward from 700 feet above the surface within a 9.5-mile radius of Ithaca Tompkins Regional Airport.

* * * * *

AEA NY E5 Endicott, NY [New]

Tri Cities Airport, NY
(lat. 42°4′43″ N, long. 76°5′47″ W)

That airspace extending upward from 700 feet above the surface within an 8-mile radius of Tri Cities Airport.

Issued in College Park, Georgia, on May 23, 2019,

Geoff Lelliott,

Acting Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2019–11496 Filed 5–31–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 121 and 135

[Docket No.: FAA–2019–0360; Notice. No. 19–05]

RIN 2120–AL12

Removal of Check Pilot Medical Certificate Requirement

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

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action would update regulatory text so as to remove inconsistencies applicable to check pilots and flight instructors in domestic, flag, and supplemental operations and flight instructors in commuter and on demand operations so that check pilots and flight instructors can continue to perform their functions in aircraft without a medical certificate, unless they are serving as required flightcrew members. The FAA also proposes to remove the medical certificate requirement for check pilots in commuter and on demand operations who perform their functions in aircraft and are not serving as required flightcrew members. Removing the medical certificate requirement would enable pilots who are otherwise qualified, to function as check pilots in aircraft.

DATES: Send comments on or before August 2, 2019.

ADDRESSES: Send comments identified by docket number FAA–2019–0360 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

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

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Nancy Lauck Claussen, Aviation Safety Inspector, Air Transportation Division, Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: 202–267–8166; email: *nancy.l.claussen@faa.gov.*

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules on aviation safety is found in Title 49 of the United States Code (49 U.S.C.). Subtitle I, Section 106 describes the authority of the FAA Administrator. The FAA issues this proposed rule under the authority Congress granted to the FAA Administrator in 49 U.S.C. 106. Section 106(f) vests final authority in the Administrator for carrying out all functions, powers, and duties of the administration relating to the promulgation of regulations and rules.

Subtitle VII of title 49 of the United States Code, Aviation Programs, describes in more detail the scope of the agency's authority. This rule is issued under the authority granted to the Administrator by Congress in 49 U.S.C. 44701 and 44705. Section 44701(a)(5) requires the Administrator to promote safe flight of civil aircraft in air commerce by prescribing regulations and setting minimum standards for other practices, methods, and procedures necessary for safety in air commerce and national security. In addition, § 44701(d)(1)(A) specifically requires the Administrator, when prescribing safety regulations, to consider ''the duty of an air carrier to provide service with the highest possible degree of safety in the public interest.'' Finally, § 44705 requires the Administrator to issue air carrier operating certificates that contain terms necessary to ensure safety in air transportation.

Executive Summary

Currently, the FAA does not require part 121 check pilots and flight instructors in airplanes and part 135 flight instructors in aircraft (airplanes and rotorcraft) to hold medical certificates, unless serving as required flightcrew members. However, this requirement is not clear because of inconsistencies in the regulatory text in parts 121 and 135. This action would amend the regulatory text to remove these inconsistencies so that it is clear that check pilots and flight instructors conducting checking and training functions in aircraft may serve without medical certificates, as long as they are not required flightcrew members.

Additionally, current regulations require check pilots under part 135 who perform their duties in aircraft to hold a medical certificate even if they are not serving as required flightcrew members. As a result, some experienced pilots who would otherwise qualify to perform part 135 check pilot functions in an aircraft, but who are not medically eligible to hold a medical certificate, are limited to conducting check pilot functions in flight simulation training devices (FSTDs). This rule proposes to eliminate the requirement for a medical certificate for check pilots who are not serving as required flightcrew members. This proposed change would increase the number of experienced pilots who would be able to qualify as part 135 check pilots on aircraft.

Table 1 summarizes the provisions included in this rule, the sections affected and impacts.

TABLE 1—SUMMARY OF PROPOSED CHANGES, SECTIONS AFFECTED AND IMPACTS

Provision	Summary	Sections affected	Impact
Check Pilot Medical Certificate Requirement			
Remove the check pilot medical certificate requirement for 135 check pilots (aircraft).	• Removes the requirement for a medical certificate in part 135 for check pilots (aircraft) who are not serving as required flightcrew members.	135.337(b)(5), (e)	Possible small cost savings for pilots who choose to stop obtaining a medical certificate.
	• Restructures section to remove duplicative requirements	135.337.	
Update current medical certificate requirements for check pilots and flight instructors in part 121 and flight instructors in part 135.	• Removes requirement for third-class medical certificate and explicitly states that only those part 121 check pilots (airplane) or flight instructors (airplane), or part 135 flight instructors (aircraft), serving as required flightcrew members must have appropriate medical certificates to serve as such.	121.411(b)(5); 121.412(b)(5); 135.338(b)(5), (e)	No impact.
	• Adds ''required'' before ''flightcrew member'' to emphasize that medical certificates are only required for check pilots and flight instructors who are serving as required flightcrew members.	135.337(e); 135.338(b)(5), (e)	
	• Restructures section to remove duplicative requirements	135.338	
Conforming and Miscellaneous Changes			
Update nomenclature	• Updates nomenclature in part 135 to change ''check airmen'' to ''check pilots'', ''check airman'' to ''check pilot'', and ''simulator'' to ''FSTD'', where appropriate.	135.113; 135.297(c)(2); 135.321(a)(2); 135.323(a)(1), (a)(4), (c); 135.324(b)(4); 135.337(a), (b), (e), (f); 135.338(a), (f); 135.339(a), (c), (d), (e), (g); 135.340(a)(2)	No impact.
	• Updates nomenclature to change ''Class I'', ''Class II'', and ''Class III'' medical certificates to ''first-class'', ''second-class'', and ''third-class'' medical certificates, respectively.	121.411(b)(5); 121.412(b)(5), (f)(1); 135.337(b)(5); 135.338(b)(5)	

I. Background

All pilots serving in part 121 and part 135 operations are required to complete competency checks and proficiency checks on a regular basis to ensure each pilot's competency in operating the specific aircraft and conducting instrument operations. These checks are conducted by *check pilots,* airmen approved by the FAA who have the appropriate knowledge, training, experience, and demonstrated ability to evaluate and to certify the knowledge and skills of other pilots. The role of the check pilot is to ensure that the flightcrew member has met competency standards before the check pilot releases the flightcrew member from training and to ensure that the flightcrew member maintains those standards while remaining in line service. A check pilot must be knowledgeable in the applicable requirements of 14 CFR parts 61, 91, 110, 119, and part 121 or 135, other applicable FAA policies, safe operating practices, and the certificate holder's policies and procedures.

A *flight instructor* is an airman designated by a part 121 or part 135 certificate holder who has the appropriate knowledge, training, experience, and demonstrated ability to

instruct flightcrew members in a flight training segment of that certificate holder's training program.

Flight instructors and check pilots typically do not serve as required crewmembers during training or checking in an FSTD. This is because they are typically staffing an instructor station from which they can oversee the simulation. They may serve as required flightcrew members during training or checking in aircraft, provided they are qualified as a pilot in command (including medical certificate requirements), and are also designated and authorized to perform training or checking functions in the specific aircraft being used. A flight instructor or check pilot is considered a required flightcrew member if the person receiving instruction is not qualified to act as pilot in command or if the type certificate of the aircraft on which instruction is being given requires more than one pilot flightcrew member and no other qualified pilot is on board.[1]

Prior to 1996, the agency required medical certificates for flight instructors and check pilots performing such functions, even if not serving as required flightcrew members.[2] In 1996, the FAA published the final rule, Training and Qualification Requirements for Check Pilots and Flight Instructors.[3] The rule recognized that some experienced part 121 and 135 pilots who would otherwise qualify as flight instructors or check pilots but were not medically eligible to hold a medical certificate could not perform their functions even in simulators.[4] The rule removed the medical certificate requirement altogether for flight instructors and check pilots in parts 135 and 121 who perform their functions in flight *simulators.*[5] However, the regulatory text was less clear as to the medical certificate requirement for flight instructors who perform their functions in aircraft in parts 135 and 121, and part 121 check pilots.

II. Discussion of the Proposed Rule

A. Part 121 Check Pilot/Flight Instructor and Part 135 Flight Instructor Medical Certificate Requirements

Currently, the agency implements §§ 121.411, 121.412, and 135.338 such that part 121 check airmen (airplane), part 121 flight instructors (airplane), and part 135 flight instructors (aircraft)[6] are not required to hold a medical certificate unless serving as required flightcrew members. There are, however, inconsistencies within the regulatory text of these provisions that has caused confusion. The agency proposes to resolve these inconsistencies with this NPRM.

Amendments to the regulatory text implementing the medical certificate requirements for check airmen and flight instructors in part 121 training programs (§§ 121.411 and 121.412) and flight instructors serving in aircraft in part 135 training programs (§ 135.338), have resulted in inconsistencies within each of these sections. For example, §§ 121.411(b)(5) and 121.412(b)(5) state that check pilots and flight instructors (airplane) must hold at least a third-class medical certificate unless serving as required crewmembers; however, §§ 121.411(e) and 121.412(e) state that check pilots and flight instructors who do not hold an appropriate medical certificate may function as check airmen, but may not serve as flightcrew members in operations under this part. In part 135, § 135.338(b)(5) states that flight instructors (aircraft) must hold at least a third-class medical certificate; however, § 135.338(e) states that an airman who does not hold a medical certificate may function as flight instructor in an aircraft if functioning as a non-required crewmember.

Allowing a part 121 check pilot, or a part 121 or part 135 flight instructor to serve as such in an airplane, without a medical certificate, when not serving as a required flightcrew member, has no negative effect on safety. Except in some circumstances in aircraft in part 135 operations, neither the check pilot nor the flight instructor sit at the controls for the aircraft unless serving as a required flightcrew member. Further, pilots serving as required flightcrew members must be fully qualified to serve as such, and must have the appropriate medical certificate. If a check pilot or flight instructor is not a required flightcrew member, they are not necessary for the operation and the flight may proceed whether or not they are present. Thus, requiring a medical certificate for check pilots and flight instructors who are not serving as required flightcrew members is an unnecessary burden. Moreover, there has been no degradation in the safe operation of aircraft resulting from the current application of the regulations during the estimated 8 years the agency has allowed eligible check airmen and flight instructors to serve without medical certificates if not serving as required crewmembers. Therefore, the FAA has determined the changes in this proposed rule would have no adverse impact on safety.

Accordingly, the FAA proposes to amend §§ 121.411(b)(5) and 121.412(b)(5) to remove the language requiring the check pilots and flight instructors to hold at least a third-class medical certificate unless serving as a required crewmember. These paragraphs will retain the requirement that the check pilots and flight instructors must hold a first- or second-class medical certificate, as appropriate, if serving as required flightcrew members.

Similarly, the FAA proposes to amend § 135.338(b)(5) to remove the language requiring flight instructors to hold at least a third-class medical certificate. For clarity and consistency with part 135 requirements to serve as a required flightcrew member, the FAA proposes to add the requirement that the flight instructor must hold a first or second-class medical certificate, as appropriate, if serving as a required flightcrew member.

B. Part 135 Check Pilot Medical Certificate Requirement

Currently, § 135.337, requires check airmen serving in part 135 in an aircraft to hold a third-class medical certificate, even if the check pilot is not serving as a required flightcrew member. Unlike the three previously discussed sections of 14 CFR (*i.e.,* §§ 121.411, 121.412 and 135.338), § 135.337 is unambiguous in establishing this third-class medical certificate requirement.

The FAA proposes to remove the requirement for a check pilot serving in part 135 in an aircraft to hold a third-class medical certificate unless the check pilot is serving as a required flightcrew member. A check pilot would need to hold an appropriate medical certificate only if serving as a required flightcrew member. Removing the requirement for a third-class medical certificate for check pilots (aircraft) who

[1] Letter of Interpretation to Willmot White from Carl Schellenberg, Assistant Chief Counsel, Regulations and Enforcement Division (Oct 5, 1978). Letter of Interpretation to Ivan Grau from Rebecca B. MacPherson, Assistant Chief Counsel for Regulations (Oct. 1, 2010); Letter of Interpretation to Louis Glenn from Rebeca B. MacPherson, Assistant Chief Counsel for Regulations (Dec. 1, 2009). (*https://www.faa.gov/about/office_org/headquarters_offices/agc/practice_areas/regulations/interpretations/*).

[2] *See e.g., Air Taxi Operators and Commercial Operators,* 42 FR 43490 (Aug. 29, 1977) and *Air Taxi Operators and Commercial Operators,* 43 FR 46742, 46777 (Oct. 10, 1978).

[3] *Training and Qualification Requirements for Check Pilots and Flight Instructors,* 61 FR 30734 (June 17, 1996).

[4] *Id.* at 30734.

[5] *Id.* at 30735.

[6] The FAA's regulations distinguish between check pilots or flight instructors performing their functions in an airplane (under part 121) or aircraft (airplanes or rotorcraft under part 135), or in a flight simulator.

are not serving as required flightcrew members would not negatively affect safety for the same reasons provided in explaining the proposal to remove the third-class medical certificate requirement for check pilots in part 121 training and similarly, would provide regulatory relief from an unnecessary burden.

This proposal would reduce regulatory burdens for part 135 operators. Removing the medical certificate requirement would provide greater operational flexibility to certificate holders and ensure that otherwise qualified, experienced persons who meet all of the training and qualification requirements necessary to function as check pilots would have the opportunity to do so.

A. Miscellaneous and Conforming Amendments

The FAA proposes the following amendments to improve the clarity and consistency of parts 135 and 121. This action proposes to change ''check airmen'' and ''check airman'' to ''check pilots'' and ''check pilot'', respectively, throughout part 135, as appropriate. In addition, this rule proposes to update the text in §§ 135.337 and 135.338 by changing ''simulator'' to ''FSTD'' where appropriate.

This action proposes to change ''Class I'', ''Class II'', and ''Class III'' medical certificates to ''first-class'', ''second-class'', and ''third-class'' medical certificates respectively, to align with the terminology used in part 61.

This action proposes to add ''required'' before ''flightcrew member'' in §§ 135.337(e) and 135.338(b)(5) and (e) to emphasize that medical certificates are only required for check pilots and flight instructors who are serving as required flightcrew members.

This action proposes to change the structure of §§ 135.337 and 135.338, which currently list the check pilot and flight instructor (aircraft) and check pilot and flight instructor (simulator) requirements separately. Since this proposed rule would remove the medical certificate requirement altogether, the only difference in the requirements between check pilot (aircraft) and check pilot (simulator) would be the recency of experience requirement. Therefore, the requirements for both check pilot (aircraft) and check pilot (simulator) would be listed once in § 135.337(b), and the recency of experience requirement for check pilot (aircraft) would be listed separately in § 135.337(c). Similarly, the requirements for flight instructor (aircraft) and flight instructor (simulator) would be listed once in § 135.338(b), and the recency of experience requirement for flight instructor (aircraft) would be listed separately in § 135.338(c).

The FAA acknowledges that similar types of miscellaneous and conforming changes that are necessary for part 135 may be necessary for part 121. The FAA will consider proposing those changes to § 121.411 and § 121.412 in a separate rulemaking action.

III. Regulatory Notices and Analyses

A. Regulatory Evaluation

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 and Executive Order 13563 direct that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96–354) requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (Pub. L. 96–39) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, this Trade Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more annually (adjusted for inflation with base year of 1995). This portion of the preamble summarizes the FAA's analysis of the economic impacts of this proposed rule.

In conducting these analyses, the FAA has determined that this proposed rule would: (1) Have savings and no additional costs, (2) not be an economically ''significant regulatory action'' as defined in section 3(f) of Executive Order 12866, (3) not have a significant economic impact on a substantial number of small entities; (4) not create unnecessary obstacles to the foreign commerce of the United States; and (5) not impose an unfunded mandate on state, local, or tribal governments, or on the private sector by exceeding the threshold identified above. These analyses are summarized below.

As previously discussed, the FAA has determined the changes in this proposed rule would have no adverse impact on safety. The FAA has found that by allowing a part 121 check pilot, or a part 121 or part 135 flight instructor to serve as such in an airplane, without a medical certificate, when not serving as a required flightcrew member, has no negative effect on safety. Except in some circumstances in aircraft in part 135 operations, neither the check pilot nor the flight instructor sit at the controls for the aircraft unless serving as a required flightcrew member. Further, pilots serving as required flightcrew members must be fully qualified to serve as such, and must have the appropriate medical certificate. If a check pilot or flight instructor is not a required flightcrew member, they are not even necessary for the operation and the flight may proceed whether or not they are present. Thus, requiring a medical certificate for check pilots and flight instructors who are not serving as required flightcrew members would result in an unnecessary burden. Moreover, there has been no degradation in the safe operation of aircraft resulting from the current application of the regulations during the estimated 8 years the agency has allowed check airmen and flight instructors to serve without medical certificates if not serving as required crewmembers.

As of June of 2018, there are roughly 1,035 part 135 check pilots.[7] Out of 1,035 part 135 check pilots, there are roughly 496 part 135 check pilots, who do not hold a medical certificate and who are therefore limited to performing check pilot duties in a flight simulator. This proposed rule would enable these check pilots, who are otherwise qualified, but may have become ineligible for a medical certificate during their employment, to function as check pilots in aircraft. While this proposed rule would expand the opportunities for these check pilots, there is not enough information on the demand for check pilots to perform their duties in an aircraft to quantify the impacts of this enabling opportunity. For example, some companies only use simulators to perform check pilots duties while others use a combination of simulators and aircraft. The FAA requests additional information and data on the expanded opportunities for affected check pilots.

Additionally, removing the requirement for a medical certificate could generate cost savings by allowing part 135 check pilots, with valid medical certificates, to discontinue

[7] National Vital Information Subsystem (NVIS) database, June 2018.

obtaining medical certificates. There are approximately 539 part 135 check pilots with valid medical certificates. Based on age and a pilot's medical condition, which determines the frequency of a medical examination, check pilots would save approximately 0.5 hours per pilot to complete the medical application (MedXpress), 0.5 hours per pilot in travel time to see an Aviation Medical Examiner (AME), and one hour for the actual medical examination.[8] Additional savings include vehicle operating costs of 0.17 cents per mile[9] based on 40 miles traveled to and from the examination, and $117 paid to the AME for the medical examination.[10] The estimated value of time for a check pilot is $111 per hour[11] resulting in potential savings per affected check pilot of $346 per medical certificate.[12]

Approximately 457 check pilots, out of the 539 check pilots with valid medical certificates, are age 40 and over. Pilots under the age of 40 renew their third-class medical certificate every five years compared to every two years for pilots age 40 and over. The FAA assumes that most pilots who would voluntarily discontinue their medical certificates are age 40 and over as this age bracket accounts for 85 percent of the check pilot population with valid medical certificates. Additionally, older applicants are more likely to apply for special issuance medical certificates, granted to applicants who do not meet the established medical standards but demonstrate they can perform without endangering public safety, than their younger counterparts.[13] Information is limited on the number of check pilots that would allow their medical certificates to expire. However, the FAA estimates that only 5 to 10 percent would no longer obtain medical certificates since check pilots still need to maintain a valid medical certificate to pilot an aircraft professionally and recreationally or serve as required flight crew. The FAA requests comment on this estimate. At 5 percent this would be 23 check pilots and at 10 percent this would be 46 check pilots. For affected check pilots age 40 and over, who would potentially take advantage of this proposed rule, this could result in undiscounted savings of $23,874 or $47,748 respectively, over a five year period of analysis as shown in the table below.[14]

TABLE 1—ESTIMATED YEARLY UNDISCOUNTED SAVINGS FOR CHECK PILOTS AGE 40 AND OVER—MEDICAL CERTIFICATE RENEWAL EVERY 2 YEARS

Year	23 Check pilots	46 Check pilots
1	$7,958	$15,916
2		
3	7,958	15,916
4		
5	7,958	15,916
Total	$23,874	$47,748

This proposed rule also updates the current regulatory text under which, the FAA allows check pilots in part 121 and flight instructors in parts 121 and 135 to serve without a medical certificate, unless they are required flightcrew members, and updates nomenclature. While the FAA does not currently require that part 121 check pilots and flight instructors and part 135 flight instructors hold medical certificates, as discussed earlier, these regulations are not clear.

The FAA has, therefore, determined that this proposed rule is not a ''significant regulatory action'' as defined in section 3(f) of Executive Order 12866.

B. Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (Public Law 96–354) (RFA) establishes ''as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration.'' The RFA covers a wide-range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a rule will have a significant economic impact on a substantial number of small entities. If the agency determines that it will, the agency must prepare a regulatory flexibility analysis as described in the RFA. However, if an agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

This proposed rule would relieve part 135 check pilots from having to obtain at least a third-class medical certificate when performing check pilot duties, in an aircraft, as long as they are not required flight crew. This change could provide cost savings to a few part 135 check pilots without additional costs. The proposed rule also would clarify related FAA regulations without substantive effect. Thus, the expected outcome would be a small positive impact on any small entity affected by this rulemaking action.

Therefore, as provided in section 605(b), the head of the FAA certifies that this rulemaking would not result in a significant economic impact on a substantial number of small entities.

C. International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these Acts, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The

[8] Estimated durations of time and miles traveled to and from examinations taken from Alternative Pilot Physical Examination and Education Requirements Regulatory Evaluation. *https://www.regulations.gov/document?D=FAA-2016-9157-0009.*

[9] Internal Revenue Service (IRS) Standard Mileage Rate for 2017, 0.17 cents per mile driven for medical or moving purposes; *https://www.irs.gov/newsroom/2017-standard-mileage-rates-for-business-medical-and-moving-announced* Dec.13, 2016.

[10] $117 aid to AME taken from Alternative Pilot Physical Examination and Education Requirements Regulatory Evaluation. *https://www.regulations.gov/document?D=FAA-2016-9157-0009.*

[11] Bureau of Labor Statistics (BLS), *National Industry-Specific Occupational Employment and Wage Estimates,* Occupational Code 53–2011 Airline Pilots, Copilots, and Flight Engineers, May 2017 *https://www.bls.gov/oes/current/naics4_488100.htm*—includes BLS Employee Compensation as of June 2017.

[12] Total savings per check pilot per medical certificate = $117 fee per pilot + $55.5 per pilot to complete the application + $111 per pilot to complete the examination + $55.5 per pilot to travel to and from the examination + $6.8 in vehicle operating costs.

[13] *https://www.federalregister.gov/documents/2007/04/10/E7-6652/modification-of-certain-medical-standards-and-procedures-and-duration-of-certain-medical.*

[14] This savings to part 135 check pilots would be at the expense of the medical practitioner.

statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. The FAA has assessed the potential effect of this proposed rule and determined that it would have only a domestic impact and therefore no effect on international trade.

D. Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (in 1995 dollars) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a ''significant regulatory action.'' The FAA currently uses an inflation-adjusted value of $155.0 million in lieu of $100 million.

This rule would not contain such a mandate. Therefore, the requirements of Title II of the Act do not apply.

E. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the FAA consider the impact of paperwork and other information collection burdens imposed on the public. According to the 1995 amendments to the Paperwork Reduction Act (5 CFR 1320.8(b)(2)(vi)), an agency may not collect or sponsor the collection of information, nor may it impose an information collection requirement unless it displays a currently valid Office of Management and Budget (OMB) control number.

The existing information collection associated with all check pilot and flight instructor medical certificates in parts 121 and 135 was approved under OMB control number 2120–0034. The information collection is used to collect medical certificate information to determine whether applicants are medically qualified to perform the duties associated with the class of medical certificate sought. The FAA has determined that removing the medical certificate requirement for part 135 check pilots (aircraft) who are currently eligible for a medical certificate, but may choose to allow their certificate to expire, would result in a negligible reduction in the information collection, as pilots would still need to maintain a valid medical certificate to pilot an aircraft or serve as required flight crew. The FAA has determined that there would be no reduction in the information collection associated with part 121 check pilots and flight instructors and part 135 flight instructors. The FAA has also determined that there would be no new requirement for information collection associated with this rule.

F. International Compatibility and Cooperation

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to conform to International Civil Aviation Organization Standards and Recommended Practices to the maximum extent practicable. The FAA has reviewed the corresponding ICAO Standards and Recommended Practices and has identified no differences with these regulations.

G. Environmental Analysis

FAA Order 1050.1F identifies FAA actions that are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act in the absence of extraordinary circumstances. The FAA has determined this rulemaking action qualifies for the categorical exclusion identified in paragraph 5–6.6f and involves no extraordinary circumstances.

IV. Executive Order Determinations

A. Executive Order 13132, Federalism

The FAA has analyzed this proposed rule under the principles and criteria of Executive Order 13132, Federalism. The agency has determined that this action would not have a substantial direct effect on the States, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government, and, therefore, would not have Federalism implications.

B. Executive Order 13211, Regulations That Significantly Affect Energy Supply, Distribution, or Use

The FAA analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). The agency has determined that it would not be a ''significant energy action'' under the executive order and would not be likely to have a significant adverse effect on the supply, distribution, or use of energy.

C. Executive Order 13609, Promoting International Regulatory Cooperation

Executive Order 13609, Promoting International Regulatory Cooperation, (77 FR 26413, May 4, 2012) promotes international regulatory cooperation to meet shared challenges involving health, safety, labor, security, environmental, and other issues and to reduce, eliminate, or prevent unnecessary differences in regulatory requirements. The FAA has analyzed this action under the policies and agency responsibilities of Executive Order 13609, and has determined that this action would have no effect on international regulatory cooperation.

D. Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs

This proposed rule is expected to be an Executive Order 13771 deregulatory action. Details on the estimated cost savings of this proposed rule can be found in the rule's economic analysis.

IV. Additional Information

A. Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. The agency also invites comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it receives on or before the closing date for comments. The agency may change this proposal in light of the comments it receives.

Proprietary or Confidential Business Information: Commenters should not file proprietary or confidential business information in the docket. Such information must be sent or delivered directly to the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this document, and marked as proprietary or confidential. If submitting information on a disk or CD ROM, mark the outside of the disk or CD ROM, and identify electronically within the disk or CD ROM the specific information that is proprietary or confidential.

Under 14 CFR 11.35(b), if the FAA is aware of proprietary information filed with a comment, the agency does not

place it in the docket. It is held in a separate file to which the public does not have access, and the FAA places a note in the docket that it has received it. If the FAA receives a request to examine or copy this information, it treats it as any other request under the Freedom of Information Act (5 U.S.C. 552). The FAA processes such a request under Department of Transportation procedures found in 49 CFR part 7.

B. Availability of Rulemaking Documents

An electronic copy of rulemaking documents may be obtained from the internet by—

- Searching the Federal eRulemaking Portal (*http://www.regulations.gov*);
- Visiting the FAA's Regulations and Policies web page at *http://www.faa.gov/regulations_policies* or
- Accessing the Government Publishing Office's web page at *http://www.fdsys.gov.*

Copies may also be obtained by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW, Washington, DC 20591, or by calling (202) 267–9677. Commenters must identify the docket or notice number of this rulemaking.

All documents the FAA considered in developing this proposed rule, including economic analyses and technical reports, may be accessed from the internet through the Federal eRulemaking Portal referenced above.

List of Subjects

14 CFR Part 121

Air carriers, Aircraft, Airmen, Aviation safety, Transportation.

14 CFR Part 135

Air taxies, Aircraft, Airmen, Aviation safety.

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend chapter I of title 14, Code of Federal Regulations as follows:

PART 121—OPERATING REQUIREMENTS: DOMESTIC, FLAG, AND SUPPLEMENTAL OPERATIONS

■ 1. The authority citation for part 121 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40113, 40119, 41706, 42301 preceding note added by Pub. L. 112–95, sec. 412, 126 Stat. 89, 44101, 44701–44702, 44705, 44709–44711, 44713, 44716–44717, 44722, 44729, 44732; 46105; Pub. L. 111–216, 124 Stat. 2348 (49 U.S.C. 44701 note); Pub. L. 112–95 126, Stat 62 (49 U.S.C. 44732 note).

■ 2. Amend § 121.411 by revising paragraph (b)(5) to read as follows:

§ 121.411 Qualifications: Check airmen (airplane) and check airmen (simulator).

* * * * *

(b) * * *

(5) Holds a first-class or second-class medical certificate, as appropriate, if serving as a required flightcrew member;

* * * * *

■ 3. Amend § 121.412 by revising paragraphs (b)(5) and (f)(1) to read as follows:

§ 121.412 Qualifications: Flight instructors (airplane) and flight instructors (simulator).

* * * * *

(b) * * *

(5) Holds a first-class or second-class medical certificate, as appropriate, if serving as a required flightcrew member; and

* * * * *

(f) * * *

(1) Fly at least two flight segments as a required crewmember for the type of airplane within the 12-month period preceding the performance of any flight instructor duty in a flight simulator (and must hold a first-class or second-class medical certificate as appropriate); or

* * * * *

PART 135—OPERATING REQUIREMENTS: COMMUTER AND ON DEMAND OPERATIONS AND RULES GOVERNING PERSONS ON BOARD SUCH AIRCRAFT

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

Authority: 49 U.S.C. 106(f), 106(g), 40113, 41706, 44701–44702, 44705, 44709, 44711–44713, 44715–44717, 44722, 44730, 45101–45105; Pub. L. 112–95, 126 Stat. 58 (49 U.S.C. 44730).

■ 5. Amend § 135.337 by revising the section heading and paragraphs (a)(1) through (a)(3), the introductory text of paragraph (b), and (b)(5) through (f) to read as follows:

§ 135.337 Qualifications: Check pilots.

(a) * * *

(1) A check pilot (aircraft) is a person who is qualified to conduct flight checks in an aircraft or FSTD for a particular type aircraft.

(2) A check pilot (simulator) is a person who is qualified to conduct flight checks in an FSTD for a particular type aircraft.

(3) Check pilot (aircraft) and check pilot (simulator) are those persons who perform the functions described in §§ 135.321(a) and 135.323(a)(4) and (c).

(b) No certificate holder may use a person, nor may any person serve as a check pilot in a training program established under this subpart unless, with respect to the aircraft type involved, that person—

* * * * *

(5) Holds a first-class or second-class medical certificate, as appropriate, if serving as a required flightcrew member; and

(6) Has been approved by the Administrator for the check pilot duties involved.

(c) No certificate holder may use a person, nor may any person serve as a check pilot (aircraft) in a training program established under this subpart unless, with respect to the aircraft type involved, that person has satisfied the recency of experience requirements of § 135.247.

(d) Completion of the requirements in paragraphs (b) (2), (3), and (4) of this section, as applicable, must be entered in the individual's training record maintained by the certificate holder.

(e) A medical certificate is not required for a person to serve as a check pilot, unless that check pilot is a required flightcrew member in an operation under this part.

(f) A check pilot (simulator) must accomplish the following—

(1) Fly at least two flight segments as a required crewmember for the type, class, or category aircraft involved within the 12-month preceding the performance of any check pilot duty in an FSTD; or

(2) Satisfactorily complete an approved line-observation program within the period prescribed by that program and that must precede the performance of any check pilot duty in an FSTD.

* * * * *

■ 6. Amend § 135.338 by revising the section heading and paragraphs (a)(1) through (a)(2), the introductory text of paragraph (b), and (b)(4) through (f) to read as follows:

§ 135.338 Qualifications: Flight instructors.

(a) * * *

(1) A flight instructor (aircraft) is a person who is qualified to instruct in an aircraft, or FSTD for a particular type, class, or category aircraft.

(2) A flight instructor (simulator) is a person who is qualified to instruct in an FSTD for a particular type, class, or category aircraft.

* * * * *

(b) No certificate holder may use a person, nor may any person serve as a flight instructor in a training program established under this subpart unless,

with respect to the type, class, or category aircraft involved, that person—

* * * * *

(4) Has satisfactorily completed the applicable training requirements of § 135.340; and

(5) Holds a first-class or second-class medical certificate, as appropriate, if serving as a required flightcrew member.

(c) No certificate holder may use a person, nor may any person serve as a flight instructor (aircraft) in a training program established under this subpart unless, with respect to the type, class, or category aircraft involved, that person has satisfied the recency of experience requirements of § 135.247.

(d) Completion of the requirements in paragraphs (b)(2), (3), and (4) of this section, as applicable, must be entered in the individual's training record maintained by the certificate holder.

(e) A medical certificate is not required for a person to serve as a check pilot, unless that check pilot is a required flightcrew member in an operation under this part.

(f) * * *

(1) Fly at least two flight segments as a required crewmember for the type, class, or category aircraft involved within the 12-month period preceding the performance of any flight instructor duty in an FSTD; or

(2) Satisfactorily complete an approved line-observation program within the period prescribed by that program preceding the performance of any flight instructor duty in an FSTD.

* * * * *

■ 7. In part 135, remove the word ''airmen'' and add, in its place, the word ''pilots'' in the following places:

■ a. Section 135.321 paragraph (a)(2);

■ b. Section 135.323 paragraph (a)(4);

■ c. Section 135.324 paragraph (b)(4); and

■ d. Section 135.339 section heading, and paragraphs (c) through (e) and (g).

■ 8. In part 135, remove the word ''airman'' and add, in its place, the word ''pilot'' in the following places:

■ a. Section 135.113 introductory text;

■ b. Section 135.297 paragraph (c)(2);

■ c. Section 135.323 paragraphs (a)(1) and (c);

■ d. Section 135.339 paragraphs (a), (c)(1), (d); and

■ e. Section 135.340 paragraph (a)(2).

Issued in Washington, DC, under the authority of 49 U.S.C. 106(f), 44701(a)(5), and 44705, on May 17, 2019.

Robert C. Carty,

Deputy Executive Director, Flight Standards Service.

[FR Doc. 2019–11086 Filed 5–31–19; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2018–0648]

RIN 1625–AA11

Revision for Regulated Navigation Area; Savannah River, GA

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to amend the regulated navigation area (RNA) on the Savannah River located between Fort Jackson, GA (32°04.93 N, 081°02.19 W) and the Savannah River Channel Entrance Sea Buoy. This document proposes to remove inapplicable and/or outdated definitions, processes and requirements in the RNA following a change in capability, infrastructure and layout of the Southern Liquefied Natural Gas (LNG) facility on the Savannah River. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before August 2, 2019.

ADDRESSES: You may submit comments identified by docket number USCG–2018–0648 using the Federal eRulemaking Portal at *https://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email LT Joseph Palmquist, Coast Guard; telephone 912–652–4353 ext. 221, email *joseph.b.palmquist@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
GT Gross tons
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code
RNA Regulated Navigation Area
COTP Captain of the Port

II. Background, Purpose, and Legal Basis

On September 10, 2007, the Coast Guard published a final rule titled ''Regulated Navigation Area: Savannah River, Savannah, GA'' at 33 CFR 165.756. (72 FR 51555). That rule established a RNA around the Southern LNG facility on the Savannah River at Elba Island. Since publishing the previous rule, there have been changes both to the facility layout and to the types of vessels that make calls to the facility. United States Coast Guard Marine Safety Unit Savannah, GA held a public meeting to solicit public input on suggested changes to this RNA. The public input we received is described in the Public Participation and Request for Comments section of this NPRM. Therefore, the U.S. Coast Guard proposes revision of and amendments to the RNA to account for these changes and to ensure the safety and security of the marine environment during LNG tankship operations. The Coast Guard proposes this rulemaking under authority in 46 U.S.C. 70041 (previously 33 U.S.C. 1231).

III. Discussion of Proposed Rule

The Commander of the Seventh Coast Guard District proposes to amend the Southern LNG facility RNA (33 CFR 165.756) as follows. The proposed rule removes the definitions of ''Fire Wire'', ''Made-up'', and ''Make-up'' because these terms do not align with the updated Oil Companies International Maine Forum (OCIMF) guidance. Additionally, the proposed rule removes requirements for LNG tankships moored inside the LNG facility slip because the facility layout and capabilities changed, rendering the requirements unnecessary. LNG tankships no longer moor outside Southern LNG facility slip; they only moor inside the facility slip.

The current regulation prohibits vessels 1600 gross tons (GT) or greater from overtaking within 1000 yards of the LNG facility slip when a LNG tankship is present within the slip. This proposed rule would instead not allow these vessels to meet nor overtake within the area adjacent to either side of the Southern LNG facility slip when an LNG tankship is present within the slip. The purpose of changing the language to ''adjacent to either side of the LNG facility'' rather than an exact distance is due to the changes of the facility layout, including the facility no longer having the capabilities or infrastructure to moor an LNG tankship outside of the Southern LNG facility slip.

This proposed rule removes the requirements for an LNG tankship that is moored outside of the Southern LNG facility slip. Since publishing the previous rule, there have been changes both to the facility infrastructure and to the types of vessels that make calls to the facility. The LNG tankships visiting

Southern LNG are only moored inside the LNG facility slip, not outside the LNG facility slip. The slip outside of the LNG facility no longer has the capability to moor LNG tankships. The change to Southern LNG facility infrastructure capacity has made these requirements unnecessary.

Finally, the proposed changes remove various requirements for vessels within the RNA. Vessels 1600 GT or greater will no longer be required to have two towing vessels when passing a LNG tankship moored outside of the LNG facility slip. Having two tugs is not required due to the change in capability, infrastructure and layout of the Southern LNG facility. Specifically, two tugs would not be required based on transiting vessel's proximity to LNG tankships moored inside the Southern LNG facility slip. Additionally, because transiting vessels can communicate and safely transit each other using VHF communications the Coast Guard has proposed removing various bridge watch requirements for vessels moored at the Southern LNG facility.

These proposed changes are necessary to ensure the safety of persons and property within the RNA during LNG tankship operations and transfers after changes in the facility layout. The changes to the regulatory text we are proposing appear at the end of this document.

IV. Regulatory Analyses

We developed this proposed amendment to the Southern LNG facility RNA at 33 CFR 165.756 after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This proposed amendment and revision has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

The economic impact of this proposed rule amendment is not significant, as the amendment does not impact the area or effective period of the current rule, but rather updates definitions and processes based on changes both to the facility layout and to the types of vessels that make calls to the LNG facility.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the RNA may be small entities, for the reasons stated in section IV.A above, this proposed rule would not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves a RNA when an LNG tankship in excess of heel is transiting the area or moored at the LNG facility. Normally such actions are categorically excluded from further review under paragraph L60(b) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. A public meeting was held on July 25, 2018 to determine whether proposed amendments or revisions to the current RNA were necessary. Members of the public, representatives from relevant marine industry, and members of the Coast Guard were in attendance. One comment was received regarding the notice of the public meeting, which was not germane to the substance of the proposed changes. A summary of comments received during the public meeting is available in the docket.

One participant proposed removing reference in the regulation to LNG tankships being moored outside of the Southern LNG facility slip as the facility no longer has this capability because the dock has been decommissioned. The Coast Guard agrees and in response to this comment proposes removal of any reference to LNG tankships being moored outside of the Southern LNG facility slip. The reference ''inside'' and ''outside'' the LNG facility remains described in various sections to avoid confusion as to what infrastructure is being referenced with the proposed rule. The proposed rule will only reference LNG tankships moored inside Southern LNG facility slip. This reference accurately describes where LNG tankship moor at Southern LNG.

One participant proposed modifying the 1,000-yard area requirement in which vessels 1,600 gross tons or greater may pass by the slip by removing the 1,000-yard requirement and inserting ''adjacent to the slip.'' The Savannah Pilots indicated their concurrence with this proposal. The Coast Guard agrees and in response proposes to remove the aforementioned 1,000-yard requirement and replace the language ''adjacent to the slip.''

One participant suggested that maintaining a bridge watch on the LNG vessel was unnecessary. The representative from Shell Shipping and Maritime indicated that nowhere else is a bridge watch maintained on an LNG vessel, and recommended eliminating the requirement. The representative from the Savannah Maritime Association requested information on how to communicate with passing vessels and the use of VHF communications. The Coast Guard agrees with the recommendation, and proposes to eliminate the requirement for a bridge watch.

One participant requested an estimated number of times the RNA would be enacted in a year. The representative from Kinder Morgan estimated 36 vessels per year would import LNG to the Southern LNG facility.

One participant suggested definitions of different types of vessels, such as barges and tankships, should be added to the current regulation. The representative from Kinder Morgan suggested that barges are not tankships and as such should not be included in the regulation. The Coast Guard agrees, and does not propose to include any such definitions at this time.

Several comments received considered the use of the RNA by barges and the need for inclusion. The Coast Guard does not believe reference to barges in the current regulation is required at this time.

The Coast Guard will consider all comments and material received during the comment period to this proposal. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to *https://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, visit *https://www.regulations.gov/privacyNotice.*

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Amend § 165.756 by:

■ a. Removing in paragraph (b), the definitions for ''Fire Wire'', ''Made-up'', and ''Make-up'';

■ b. Removing paragraphs (d)(2), (d)(4), (d)(5) and (d)(6); redesignate paragraph (d)(3) as paragraph (d)(2);

■ c. Removing in newly designated paragraphs (d)(2)(i) and (ii), the words ''as directed by the LNG vessel bridge watch required in paragraph (d)(5) of this section.'' and

■ d. Adding new paragraph (d)(3) to read as follows:

§ 165.756 Regulated Navigation Area; Savannah River, Georgia.

* * * * *

(d) * * *

(3) *Requirements for other vessels while within the RNA.* (i) Vessels 1,600 gross tons or greater shall at a minimum, transit at bare steerageway when within an area 1,000 yards on either side of the LNG facility slip to minimize potential wake or surge damage to the LNG facility and vessel(s) within the slip.

(ii) Vessels 1,600 gross tons or greater shall not meet nor overtake within the area adjacent to either side of the LNG facility slip when an LNG tankship is present within the slip.

(iii) Except for vessels involved in those operations noted in paragraph (c) of this section entitled Applicability, no vessel shall enter the LNG facility slip at any time without the permission of the Captain of the Port.

* * * * *

Dated: May 24, 2019.

P.J. Brown,

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

[FR Doc. 2019–11258 Filed 5–31–19; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–OLEM–2019–0077 and 0078; FRL–9994–59–OLEM]

National Priorities List

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Comprehensive Environmental Response, Compensation, and Liability Act (''CERCLA'' or ''the Act''), as amended, requires that the National Oil and Hazardous Substances Pollution Contingency Plan (''NCP'') include a list of national priorities among the known releases or threatened releases of hazardous substances, pollutants or contaminants throughout the United States. The National Priorities List (''NPL'') constitutes this list. The NPL is intended primarily to guide the Environmental Protection Agency (''EPA'' or ''the agency'') in determining which sites warrant further investigation. These further investigations will allow the EPA to assess the nature and extent of public health and environmental risks associated with the site and to determine what CERCLA-financed remedial action(s), if any, may be appropriate. This rulemaking proposes to add two sites to the General Superfund section of the NPL.

DATES: Comments regarding any of these proposed listings must be submitted (postmarked) on or before August 2, 2019.

ADDRESSES: Identify the appropriate docket number from the table below.

DOCKET IDENTIFICATION NUMBERS BY SITE

Site name	City/county, state	Docket ID No.
Schroud Property	Chicago, IL	EPA–HQ–OLEM–2019–0077
Arsenic Mine	Kent, NY	EPA–HQ–OLEM–2019–0078

You may send comments, identified by the appropriate docket number, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov/* (our preferred method). Follow the online instructions for submitting comments.
- *Agency website: https://www.epa.gov/superfund/current-npl-updates-new-proposed-npl-sites-and-new-npl-sites.*

Scroll down to the site for which you would like to submit comments and click the ''Comment Now'' link.

- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, Superfund Docket, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- *Hand Delivery/Courier:* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m.–4:30 p.m., Monday–Friday (except Federal Holidays).

Instructions: All submissions received must include the appropriate Docket ID No. for site(s) for which you are submitting comments. Comments received may be posted without change to *https://www.regulations.gov/,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the ''Public Review/Public Comment'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Terry Jeng, phone: (703) 603–8852, email: *jeng.terry@epa.gov,* Assessment and Remediation Division, Office of Superfund Remediation and Technology Innovation, Mail code 5204P, Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; or the Superfund Hotline, phone (800) 424–9346 or (703) 412–9810 in the Washington, DC, metropolitan area.

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I. Public Review/Public Comment

A. May I review the documents relevant to this proposed rule?

Yes, documents that form the basis for the EPA's evaluation and scoring of the sites in this proposed rule are contained in public dockets located both at the EPA Headquarters in Washington, DC, and in the regional offices. These documents are also available by electronic access at *https://www.regulations.gov* (see instructions in the **ADDRESSES** section above).

B. How do I access the documents?

You may view the documents, by appointment only, in the Headquarters

or the regional dockets after the publication of this proposed rule. The hours of operation for the Headquarters docket are from 8:30 a.m. to 4:30 p.m., Monday through Friday excluding federal holidays. Please contact the regional dockets for hours.

The following is the contact information for the EPA Headquarters Docket: Docket Coordinator, Headquarters, U.S. Environmental Protection Agency, Superfund (CERCLA) Docket Office, 1301 Constitution Avenue NW, William Jefferson Clinton Building West, Room 3334, Washington, DC 20004; 202/566–0276. (Please note this is a visiting address only. Mail comments to the EPA Headquarters as detailed at the beginning of this preamble.)

The contact information for the regional dockets is as follows:

- Holly Inglis, Region 1 (CT, ME, MA, NH, RI, VT), U.S. EPA, Superfund Records and Information Center, 5 Post Office Square, Suite 100, Boston, MA 02109–3912; 617/918–1413.
- Ildefonso Acosta, Region 2 (NJ, NY, PR, VI), U.S. EPA, 290 Broadway, New York, NY 10007–1866; 212/637–4344.
- Lorie Baker (ASRC), Region 3 (DE, DC, MD, PA, VA, WV), U.S. EPA, Library, 1650 Arch Street, Mailcode 3HS12, Philadelphia, PA 19103; 215/814–3355.
- Cathy Amoroso, Region 4 (AL, FL, GA, KY, MS, NC, SC, TN), U.S. EPA, 61 Forsyth Street SW, Mailcode 9T25, Atlanta, GA 30303; 404/562–8637.
- Todd Quesada, Region 5 (IL, IN, MI, MN, OH, WI), U.S. EPA Superfund Division Librarian/SFD Records Manager SRC–7J, Metcalfe Federal Building, 77 West Jackson Boulevard, Chicago, IL 60604; 312/886–4465.
- Brenda Cook, Region 6 (AR, LA, NM, OK, TX), U.S. EPA, 1445 Ross Avenue, Suite 1200, Mailcode 6SFTS, Dallas, TX 75202–2733; 214/665–7436.
- Kumud Pyakuryal, Region 7 (IA, KS, MO, NE), U.S. EPA, 11201 Renner Blvd., Mailcode SUPRSTAR, Lenexa, KS 66219; 913/551–7956.
- Victor Ketellapper, Region 8 (CO, MT, ND, SD, UT, WY), U.S. EPA, 1595 Wynkoop Street, Mailcode 8EPR–B, Denver, CO 80202–1129; 303/312–6578.
- Sharon Bowen, Region 9 (AZ, CA, HI, NV, AS, GU, MP), U.S. EPA, 75 Hawthorne Street, Mailcode SFD 6–1, San Francisco, CA 94105; 415/947–4250.
- Ken Marcy, Region 10 (AK, ID, OR, WA), U.S. EPA, 1200 6th Avenue, Mailcode ECL–112, Seattle, WA 98101; 206/463–1349.

You may also request copies from the EPA Headquarters or the regional dockets. An informal request, rather than a formal written request under the Freedom of Information Act, should be the ordinary procedure for obtaining copies of any of these documents. Please note that due to the difficulty of reproducing oversized maps, oversized maps may be viewed only in-person; since the EPA dockets are not equipped to both copy and mail out such maps or scan them and send them out electronically.

You may use the docket at *https://www.regulations.gov* to access documents in the Headquarters docket. Please note that there are differences between the Headquarters docket and the regional dockets and those differences are outlined in this preamble below.

C. What documents are available for public review at the EPA Headquarters docket?

The Headquarters docket for this proposed rule contains the following for the sites proposed in this rule: HRS score sheets; documentation records describing the information used to compute the score; information for any sites affected by particular statutory requirements or the EPA listing policies; and a list of documents referenced in the documentation record.

D. What documents are available for public review at the EPA regional dockets?

The regional dockets for this proposed rule contain all of the information in the Headquarters docket plus the actual reference documents containing the data principally relied upon and cited by the EPA in calculating or evaluating the HRS score for the sites. These reference documents are available only in the regional dockets.

E. How do I submit my comments?

Follow the online instructions detailed above in the **ADDRESSES** section for submitting comments. Once submitted, comments cannot be edited or removed from the docket. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

F. What happens to my comments?

The EPA considers all comments received during the comment period. Significant comments are typically addressed in a support document that the EPA will publish concurrently with the **Federal Register** document if, and when, the site is listed on the NPL.

G. What should I consider when preparing my comments?

Comments that include complex or voluminous reports, or materials prepared for purposes other than HRS scoring, should point out the specific information that the EPA should consider and how it affects individual HRS factor values or other listing criteria (*Northside Sanitary Landfill* v. *Thomas,* 849 F.2d 1516 (D.C. Cir. 1988)). The EPA will not address voluminous comments that are not referenced to the HRS or other listing criteria. The EPA will not address comments unless they indicate which component of the HRS documentation record or what particular point in the EPA's stated eligibility criteria is at issue.

H. May I submit comments after the public comment period is over?

Generally, the EPA will not respond to late comments. The EPA can guarantee only that it will consider those comments postmarked by the close of the formal comment period. The EPA has a policy of generally not delaying a final listing decision solely to accommodate consideration of late comments.

I. May I view public comments submitted by others?

During the comment period, comments are placed in the Headquarters docket and are available to the public on an ''as received'' basis. A complete set of comments will be available for viewing in the regional dockets approximately one week after the formal comment period closes.

All public comments, whether submitted electronically or in paper form, will be made available for public viewing in the electronic public docket at *https://www.regulations.gov* as the EPA receives them and without change, unless the comment contains copyrighted material, confidential business information (CBI) or other

information whose disclosure is restricted by statute. Once in the public dockets system, select ''search,'' then key in the appropriate docket ID number.

J. May I submit comments regarding sites not currently proposed to the NPL?

In certain instances, interested parties have written to the EPA concerning sites that were not at that time proposed to the NPL. If those sites are later proposed to the NPL, parties should review their earlier concerns and, if still appropriate, resubmit those concerns for consideration during the formal comment period. Site-specific correspondence received prior to the period of formal proposal and comment will not generally be included in the docket.

II. Background

A. What are CERCLA and SARA?

In 1980, Congress enacted the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. 9601–9675 (''CERCLA'' or ''the Act''), in response to the dangers of uncontrolled releases or threatened releases of hazardous substances, and releases or substantial threats of releases into the environment of any pollutant or contaminant that may present an imminent or substantial danger to the public health or welfare. CERCLA was amended on October 17, 1986, by the Superfund Amendments and Reauthorization Act (''SARA''), Public Law 99–499, 100 Stat. 1613 *et seq.*

B. What is the NCP?

To implement CERCLA, the EPA promulgated the revised National Oil and Hazardous Substances Pollution Contingency Plan (''NCP''), 40 CFR part 300, on July 16, 1982 (47 FR 31180), pursuant to CERCLA section 105 and Executive Order 12316 (46 FR 42237, August 20, 1981). The NCP sets guidelines and procedures for responding to releases and threatened releases of hazardous substances or releases or substantial threats of releases into the environment of any pollutant or contaminant that may present an imminent or substantial danger to the public health or welfare. The EPA has revised the NCP on several occasions. The most recent comprehensive revision was on March 8, 1990 (55 FR 8666).

As required under section 105(a)(8)(A) of CERCLA, the NCP also includes ''criteria for determining priorities among releases or threatened releases throughout the United States for the purpose of taking remedial action and, to the extent practicable taking into account the potential urgency of such action, for the purpose of taking removal action.'' ''Removal'' actions are defined broadly and include a wide range of actions taken to study, clean up, prevent or otherwise address releases and threatened releases of hazardous substances, pollutants or contaminants (42 U.S.C. 9601(23)).

C. What is the National Priorities List (NPL)?

The NPL is a list of national priorities among the known or threatened releases of hazardous substances, pollutants or contaminants throughout the United States. The list, which is appendix B of the NCP (40 CFR part 300), was required under section 105(a)(8)(B) of CERCLA, as amended. Section 105(a)(8)(B) defines the NPL as a list of ''releases'' and the highest priority ''facilities'' and requires that the NPL be revised at least annually. The NPL is intended primarily to guide the EPA in determining which sites warrant further investigation to assess the nature and extent of public health and environmental risks associated with a release of hazardous substances, pollutants or contaminants. The NPL is only of limited significance, however, as it does not assign liability to any party or to the owner of any specific property. Also, placing a site on the NPL does not mean that any remedial or removal action necessarily need be taken.

For purposes of listing, the NPL includes two sections, one of sites that are generally evaluated and cleaned up by the EPA (the ''General Superfund section''), and one of sites that are owned or operated by other federal agencies (the ''Federal Facilities section''). With respect to sites in the Federal Facilities section, these sites are generally being addressed by other federal agencies. Under Executive Order 12580 (52 FR 2923, January 29, 1987) and CERCLA section 120, each federal agency is responsible for carrying out most response actions at facilities under its own jurisdiction, custody or control, although the EPA is responsible for preparing a Hazard Ranking System (''HRS'') score and determining whether the facility is placed on the NPL.

D. How are sites listed on the NPL?

There are three mechanisms for placing sites on the NPL for possible remedial action (see 40 CFR 300.425(c) of the NCP): (1) A site may be included on the NPL if it scores sufficiently high on the HRS, which the EPA promulgated as appendix A of the NCP (40 CFR part 300). The HRS serves as a screening tool to evaluate the relative potential of uncontrolled hazardous substances, pollutants or contaminants to pose a threat to human health or the environment. On December 14, 1990 (55 FR 51532), the EPA promulgated revisions to the HRS partly in response to CERCLA section 105(c), added by SARA. On January 9, 2017 (82 FR 2760), a subsurface intrusion component was added to the HRS to enable the EPA to consider human exposure to hazardous substances or pollutants and contaminants that enter regularly occupied structures through subsurface intrusion when evaluating sites for the NPL. The current HRS evaluates four pathways: Ground water, surface water, soil exposure and subsurface intrusion, and air. As a matter of agency policy, those sites that score 28.50 or greater on the HRS are eligible for the NPL. (2) Pursuant to 42 U.S.C. 9605(a)(8)(B), each state may designate a single site as its top priority to be listed on the NPL, without any HRS score. This provision of CERCLA requires that, to the extent practicable, the NPL include one facility designated by each state as the greatest danger to public health, welfare or the environment among known facilities in the state. This mechanism for listing is set out in the NCP at 40 CFR 300.425(c)(2). (3) The third mechanism for listing, included in the NCP at 40 CFR 300.425(c)(3), allows certain sites to be listed without any HRS score, if all of the following conditions are met:

- The Agency for Toxic Substances and Disease Registry (ATSDR) of the U.S. Public Health Service has issued a health advisory that recommends dissociation of individuals from the release.
- The EPA determines that the release poses a significant threat to public health.
- The EPA anticipates that it will be more cost-effective to use its remedial authority than to use its removal authority to respond to the release.

The EPA promulgated an original NPL of 406 sites on September 8, 1983 (48 FR 40658) and generally has updated it at least annually.

E. What happens to sites on the NPL?

A site may undergo remedial action financed by the Trust Fund established under CERCLA (commonly referred to as the ''Superfund'') only after it is placed on the NPL, as provided in the NCP at 40 CFR 300.425(b)(1). (''Remedial actions'' are those ''consistent with permanent remedy, taken instead of or in addition to removal actions. * * *'' 42 U.S.C. 9601(24).) However, under 40 CFR 300.425(b)(2) placing a site on the NPL ''does not imply that monies will be expended.'' The EPA may pursue other

appropriate authorities to respond to the releases, including enforcement action under CERCLA and other laws.

F. Does the NPL define the boundaries of sites?

The NPL does not describe releases in precise geographical terms; it would be neither feasible nor consistent with the limited purpose of the NPL (to identify releases that are priorities for further evaluation), for it to do so. Indeed, the precise nature and extent of the site are typically not known at the time of listing.

Although a CERCLA ''facility'' is broadly defined to include any area where a hazardous substance has ''come to be located'' (CERCLA section 101(9)), the listing process itself is not intended to define or reflect the boundaries of such facilities or releases. Of course, HRS data (if the HRS is used to list a site) upon which the NPL placement was based will, to some extent, describe the release(s) at issue. That is, the NPL site would include all releases evaluated as part of that HRS analysis.

When a site is listed, the approach generally used to describe the relevant release(s) is to delineate a geographical area (usually the area within an installation or plant boundaries) and identify the site by reference to that area. However, the NPL site is not necessarily coextensive with the boundaries of the installation or plant, and the boundaries of the installation or plant are not necessarily the ''boundaries'' of the site. Rather, the site consists of all contaminated areas within the area used to identify the site, as well as any other location where that contamination has come to be located, or from where that contamination came.

In other words, while geographic terms are often used to designate the site (*e.g.,* the ''Jones Co. Plant site'') in terms of the property owned by a particular party, the site, properly understood, is not limited to that property (*e.g.,* it may extend beyond the property due to contaminant migration), and conversely may not occupy the full extent of the property (*e.g.,* where there are uncontaminated parts of the identified property, they may not be, strictly speaking, part of the ''site''). The ''site'' is thus neither equal to, nor confined by, the boundaries of any specific property that may give the site its name, and the name itself should not be read to imply that this site is coextensive with the entire area within the property boundary of the installation or plant. In addition, the site name is merely used to help identify the geographic location of the contamination, and is not meant to constitute any determination of liability at a site. For example, the name ''Jones Co. Plant site,'' does not imply that the Jones Company is responsible for the contamination located on the plant site.

The EPA regulations provide that the remedial investigation (''RI'') ''is a process undertaken . . . to determine the nature and extent of the problem presented by the release'' as more information is developed on site contamination, and which is generally performed in an interactive fashion with the feasibility Study (''FS'') (40 CFR 300.5). During the RI/FS process, the release may be found to be larger or smaller than was originally thought, as more is learned about the source(s) and the migration of the contamination. However, the HRS inquiry focuses on an evaluation of the threat posed and therefore the boundaries of the release need not be exactly defined. Moreover, it generally is impossible to discover the full extent of where the contamination ''has come to be located'' before all necessary studies and remedial work are completed at a site. Indeed, the known boundaries of the contamination can be expected to change over time. Thus, in most cases, it may be impossible to describe the boundaries of a release with absolute certainty.

Further, as noted previously, NPL listing does not assign liability to any party or to the owner of any specific property. Thus, if a party does not believe it is liable for releases on discrete parcels of property, it can submit supporting information to the agency at any time after it receives notice it is a potentially responsible party.

For these reasons, the NPL need not be amended as further research reveals more information about the location of the contamination or release.

G. How are sites removed from the NPL?

The EPA may delete sites from the NPL where no further response is appropriate under Superfund, as explained in the NCP at 40 CFR 300.425(e). This section also provides that the EPA shall consult with states on proposed deletions and shall consider whether any of the following criteria have been met:

(i) Responsible parties or other persons have implemented all appropriate response actions required;

(ii) All appropriate Superfund-financed response has been implemented and no further response action is required; or

(iii) The remedial investigation has shown the release poses no significant threat to public health or the environment, and taking of remedial measures is not appropriate.

H. May the EPA delete portions of sites from the NPL as they are cleaned up?

In November 1995, the EPA initiated a policy to delete portions of NPL sites where cleanup is complete (60 FR 55465, November 1, 1995). Total site cleanup may take many years, while portions of the site may have been cleaned up and made available for productive use.

I. What is the Construction Completion List (CCL)?

The EPA also has developed an NPL construction completion list (''CCL'') to simplify its system of categorizing sites and to better communicate the successful completion of cleanup activities (58 FR 12142, March 2, 1993). Inclusion of a site on the CCL has no legal significance.

Sites qualify for the CCL when: (1) Any necessary physical construction is complete, whether or not final cleanup levels or other requirements have been achieved; (2) the EPA has determined that the response action should be limited to measures that do not involve construction (*e.g.,* institutional controls); or (3) the site qualifies for deletion from the NPL. For more information on the CCL, see the EPA's internet site at *https://www.epa.gov/superfund/construction-completions-national-priorities-list-npl-sites-number.*

J. What is the Sitewide Ready for Anticipated Use measure?

The Sitewide Ready for Anticipated Use measure (formerly called Sitewide Ready-for-Reuse) represents important Superfund accomplishments and the measure reflects the high priority the EPA places on considering anticipated future land use as part of the remedy selection process. See Guidance for Implementing the Sitewide Ready-for-Reuse Measure, May 24, 2006, OSWER 9365.0–36. This measure applies to final and deleted sites where construction is complete, all cleanup goals have been achieved, and all institutional or other controls are in place. The EPA has been successful on many occasions in carrying out remedial actions that ensure protectiveness of human health and the environment for current and future land uses, in a manner that allows contaminated properties to be restored to environmental and economic vitality. For further information, please go to *https://www.epa.gov/superfund/about-superfund-cleanup-process#tab-9.*

K. What is state/tribal correspondence concerning NPL listing?

In order to maintain close coordination with states and tribes in the NPL listing decision process, the EPA's policy is to determine the position of the states and tribes regarding sites that the EPA is considering for listing. This consultation process is outlined in two memoranda that can be found at the following website: *https://www.epa.gov/superfund/statetribal-correspondence-concerning-npl-site-listing.*

The EPA has improved the transparency of the process by which state and tribal input is solicited. The EPA is using the Web and where appropriate more structured state and tribal correspondence that (1) explains the concerns at the site and the EPA's rationale for proceeding; (2) requests an explanation of how the state intends to address the site if placement on the NPL is not favored; and (3) emphasizes the transparent nature of the process by informing states that information on their responses will be publicly available.

A model letter and correspondence from this point forward between the EPA and states and tribes where applicable, is available on the EPA's website at *https://www.epa.gov/superfund/statetribal-correspondence-concerning-npl-site-listing.*

III. Contents of This Proposed Rule

A. Proposed Additions to the NPL

In this proposed rule, the EPA is proposing to add two sites to the NPL, both to the General Superfund section. Schroud Property is being proposed for NPL addition based on an HRS score of 28.50 or above. Arsenic Mine is being proposed based on ATSDR health advisory criteria.

The sites are presented in the table below.

GENERAL SUPERFUND SECTION

State	Site name	City/county
IL	Schroud Property	Chicago.
NY ...	Arsenic Mine	Kent.

IV. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.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.

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

This action is not expected to be 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 an information collection burden under the PRA. This rule does not contain any information collection requirements that require approval of the OMB.

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. This action will not impose any requirements on small entities. This rule listing sites on the NPL does not impose any obligations on any group, including small entities. This rule also does not establish standards or requirements that any small entity must meet and imposes no direct costs on any small entity. Whether an entity, small or otherwise, is liable for response costs for a release of hazardous substances depends on whether that entity is liable under CERCLA 107(a). Any such liability exists regardless of whether the site is listed on the NPL through this rulemaking.

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. This action imposes no enforceable duty on any state, local or tribal governments or the private sector. Listing a site on the NPL does not itself impose any costs. Listing does not mean that the EPA necessarily will undertake remedial action. Nor does listing require any action by a private party, state, local or tribal governments or determine liability for response costs. Costs that arise out of site responses result from future site-specific decisions regarding what actions to take, not directly from the act of placing a site on the NPL

F. Executive Order 13132: Federalism

This rule does not have federalism implications. 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. Listing a site on the NPL does not impose any costs on a tribe or require a tribe to take remedial action. Thus, Executive Order 13175 does not apply to this action.

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

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because this action itself is procedural in nature (adds sites to a list) and does not, in and of itself, provide protection from environmental health and safety risks. Separate future regulatory actions are required for mitigation of environmental health and safety risks.

I. Executive Order 13211: Actions 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)

This rulemaking does not involve technical standards.

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

The EPA believes the human health or environmental risk addressed by this action will not have potential disproportionately high and adverse human health or environmental effects on minority, low-income or indigenous populations because it does not affect the level of protection provided to human health or the environment. As discussed in Section I.C. of the preamble to this action, the NPL is a list of national priorities. The NPL is intended primarily to guide the EPA in

determining which sites warrant further investigation to assess the nature and extent of public health and environmental risks associated with a release of hazardous substances, pollutants or contaminants. The NPL is of only limited significance as it does not assign liability to any party. Also, placing a site on the NPL does not mean that any remedial or removal action necessarily need be taken.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Natural resources, Oil pollution, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: May 23, 2019.

Barry N. Breen,

Acting Assistant Administrator, Office of Land and Emergency Management.

For the reasons set forth in the preamble, EPA proposes to amend 40 CFR part 300 as follows:

PART 300—NATIONAL OIL AND HAZARDOUS SUBSTANCES POLLUTION CONTINGENCY PLAN

■ 1. The authority citation for part 300 continues to read as follows:

Authority: 33 U.S.C. 1321(d); 42 U.S.C. 9601–9657; E.O. 13626, 77 FR 56749, 3 CFR, 2013 Comp., p. 306; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

■ 2. Table 1 of appendix B to part 300 is proposed to be amended by adding the entries for ''Schroud Property'', and ''Arsenic Mine'' in alphabetical order by state.

Appendix B to Part 300—National Priorities List

TABLE 1—GENERAL SUPERFUND SECTION

State	Site name	City/county	Notes [a]
*	*	*	*
IL	Schroud Property	Chicago.	
*	*	*	*
NY	Arsenic Mine	Kent	A
*	*	*	*

[a] A = Based on issuance of health advisory by Agency for Toxic Substances and Disease Registry (if scored, HRS score need not be greater than or equal to 28.50).

* * * * *

[FR Doc. 2019–11408 Filed 5–31–19; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1, 2, 25 and 27

[GN Docket No. 18–122; RM–11791; RM–11778; DA 19–385]

International Bureau and Wireless Telecommunications Bureau Seek Focused Additional Comment in 3.7–4.2 GHz Band Proceeding

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the International Bureau and Wireless Telecommunications Bureau invite interested parties to submit more focused additional comment on the issues set forth below and any other issues commenters wish to raise concerning proposals for enabling additional terrestrial use of the 3.7–4.2 GHz band (C-band). As the Commission explained in its July 2018 Notice of Proposed Rulemaking (*NPRM*), the Commission's efforts to make this mid-band spectrum available for more flexible use will help close the digital divide by providing wireless broadband connectivity across the nation and secure U.S. leadership in next-generation services, including fifth-generation (5G) wireless and the Internet of Things.

DATES: Comments are due on or before July 3, 2019; reply comments on or before July 18, 2019.

ADDRESSES: You may submit comments, identified by GN Docket No. 18–122, by any of the following methods:

- *Federal Communications Commission's website: https://www.fcc.gov/ecfs/.* Follow the instructions for submitting comments.
- *People With Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: *FCC504@fcc.gov,* phone: 202–418–0530 or TTY: 202–418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Matthew Pearl of the Wireless Telecommunications Bureau, at *Matthew.Pearl@fcc.gov* or (202) 418–2607, or Jim Schlichting of the International Bureau, at *Jim.Schlichting@fcc.gov* or (202) 418–1547. For information regarding Initial Paperwork Reduction Act, contact Cathy Williams, Office of Managing Director, at (202) 418–2918 or *Cathy.Williams@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's document, DA 19–385, (IB, WTB May 3, 2019), GN Docket No. 18–122, RM–11791, RM–11778. The complete text of this document, as well as comments, reply comments, and *ex parte* submissions, is available for public inspection and copying from 8 a.m. to 4:30 p.m. Eastern Time (ET) Monday through Thursday or from 8 a.m. to 11:30 a.m. ET on Fridays in the FCC Reference Information Center, 445 12th Street SW, Room CY–A257, Washington, DC 20554. The complete text is available on the Commission's website at *http://wireless.fcc.gov,* or by using the search function on the ECFS web page at *http://www.fcc.gov/cgb/ecfs/.* Alternative formats are available to persons with disabilities by calling the Consumer & Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (tty).

Comment Filing Procedures

Pursuant to sections 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and replies on or before the dates indicated on the first page of this document. Comments and replies may be filed using the Commission's

Electronic Comment Filing System (ECFS).

• *Electronic Filers:* Comments may be filed electronically using the internet by accessing ECFS: *https://www.fcc.gov/ecfs/.* Filers should follow the instructions provided on the website for submitting comments. In completing the transmittal screen, filers should include their full name, U.S. Postal Service mailing address, and the applicable docket number, GN Docket No. 18–122.

• *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

○ All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th Street SW, Room TW–A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of before entering the building.

○ Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701.

○ U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW, Washington DC 20554.

People With Disabilities. To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at 202–418–0530 (voice), 844–432–2275 (videophone), or 202–418–0432 (TTY).

Initial Paperwork Reduction Act of 1995 Analysis

This document does not contain proposed information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden for small business concerns with fewer than 25 employees, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

Ex Parte Rules

Pursuant to section 1.1200(a) of the Commission's rules, this Public Notice shall be treated as a ''permit-but-disclose'' proceeding in accordance with the Commission's *ex parte* rules. Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with section 1.1206(b). In proceedings governed by section 1.49(f) or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.,* .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules.

Synopsis

1. In the *NPRM,*[1] the Commission sought to balance the desire to make this spectrum available for new terrestrial wireless uses in a rapid and efficient manner with the need to accommodate incumbent Fixed Satellite Service (FSS) and Fixed Service (FS) operations in the band. To that end, the Commission sought comment on both market-based and auction-based approaches for repurposing a portion or all of the C-band for flexible use licenses, as well as approaches that combine elements of market- and auction-based clearing mechanisms. Commenters have weighed in by supporting or opposing a variety of clearing mechanisms, and their comments raise additional issues concerning the Commission's authority to employ elements of those mechanisms. The Commission now invites focused additional comment on the issues set forth below and any other issues commenters wish to raise concerning proposals for enabling additional terrestrial use of the C-band.

What are the enforceable interference protection rights, if any, granted to space station operators against co-primary terrestrial operations? Do those rights depend on the extent incumbent earth stations receive their transmissions within the United States? And what limits, if any, does section 316 of the Act place on the proposals raised by the Commission in this *NPRM* or by the commenters in this docket?

2. Space station operators use the 3.7–4.2 GHz band for downlink operations. Before transmitting in the band, a space station operator must receive either a license from the Commission or a license from a non-U.S. government along with a grant of market access by the Commission. Requests for U.S. market access through non-U.S.-licensed space stations require the same legal and technical information that the Commission's rules require for a license application for that space station. Whether a space station operator is a licensee or recipient of a market access grant, modifications to U.S. operations require Commission review. Importantly, the Commission's rules permit space station operators to transmit in the 3.7–4.2 GHz band on a nonexclusive basis from specific orbital locations.

3. Fixed terrestrial users have co-primary use of the 3.7–4.2 GHz band. Fixed terrestrial licensees may be assigned 20 megahertz paired channels for point-to-point common carrier or private operational fixed microwave links in the 3.7–4.2 GHz band and must comply with the frequency coordination procedures set forth in part 101 to be entitled to interference protection.

4. To implement a sharing framework for the band, the Commission's rules offer receive-only earth stations the option to register for protection against

[1] *See Expanding Flexible Use of the 3.7–4.2 GHz Band,* Order and Notice of Proposed Rulemaking, 33 FCC Rcd 6915 (2018), 83 FR. 42043 (Aug. 20, 2018) (*Order*), 83 FR. 44128 (Aug. 29, 2018) (*NPRM*).

terrestrial fixed stations.[2] Such registration occurs by filing applications accompanied by an exhibit demonstrating coordination with terrestrial stations. The purpose of this coordination requirement is to establish the baseline level of interference that an earth station must accept in frequency bands shared by the fixed terrestrial and fixed satellite services on a co-primary basis. The coordination results entitle the earth station to the interference protection levels agreed to during coordination. Or as the Commission's rules put it, ''protection from impermissible levels of interference to the reception of signals by earth stations in the Fixed-Satellite Service from terrestrial stations in a co-equally shared band is provided through the authorizations granted under this part.''

5. Against this backdrop, the Commission seeks targeted comment on the extent to which satellite space station operators have enforceable rights against harmful interference from terrestrial stations in the C-band under their space station licenses and market access grants. For C-band satellite space station operators, what is the scope of enforceable rights, if any, that they have under their space station licenses and market access grants? Is there any distinction between the enforceable rights, if any, accorded to U.S.-licensed space stations and non-U.S.-licensed space stations that have been duly approved for U.S. market access? Commenters should discuss the specific statutory or regulatory provisions granting any such enforceable rights.

6. The C-Band Alliance argues that C-band satellite space station operators with no U.S. customers and no U.S. revenues should not be compensated in the C-band transition process. In contrast, the small satellite operators argue that any transition plan must ''[c]ompensate fairly all satellite operators with satellites authorized by the Commission to provide C-band service in the United States for the loss of valuable spectrum that they are currently authorized to use to offer services. . . .'' Do the enforceable rights, if any, of space station operators depend on the extent incumbent earth stations receive their transmissions within the United States? For instance, do space station operators have a right to transmit free from harmful interference only where there are registered earth stations receiving their signal? Do they have a right to transmit free from harmful interference anywhere in the contiguous United States? Do they only have the right to transmit on a non-exclusive basis? Or do they have some broader right to preclude the Commission from adopting any policy that would impair their satellite service distribution business? To put it another way, to what extent are the enforceable rights of a space station operator dependent on, or derivative from, the rights of licensed or registered receive-only earth stations that receive that space station operator's signal?

7. T-Mobile has suggested that, as a technical matter, new, flexible-use terrestrial operations would not suffer harmful interference from downlink signals but could cause harmful interference to licensed or registered receive-only earth stations in the band. Is this correct? If so, how should it impact the Commission's analysis given that new flexible-use operations could cause harmful interference to licensed or registered receive-only earth stations in the band?

8. Section 316 of the Act gives the Commission authority to modify entire classes of station licenses by rulemaking or adjudication, but that this authority has been interpreted not to extend to any ''fundamental change'' to the terms of a license. What obligations, if any, does section 316 of the Communications Act (or any other provision of the Act) impose on the Commission with respect to space station operators if the Commission were to authorize new terrestrial operations in the band under any of the proposals in the *NPRM* or the record? Does section 316 require that the Commission ensure the receipt of downlink transmissions where there are registered earth stations receiving a space station's signal? Does section 316 require the availability of comparable facilities for such locations? Does section 316 create obligations in areas where there are no registered earth stations?

9. So long as a satellite operator's transmission rights are not disturbed, would section 316 even apply if the Commission authorized additional terrestrial use that could interfere with the receipt of the signal? If so, under what circumstances and to what extent? And would section 316 apply to a satellite operator that was permitted, after the Commission adopted changes to the band in this rulemaking, to continue to transmit on a non-exclusive, shared basis?

10. If section 316 does impose obligations on the Commission regarding satellite licensees or market access grantees, how should the Commission measure comparability in the context of these proposals? Of what relevance here are the Commission's prior actions to ensure that incumbents required to vacate spectrum receive comparable facilities, or to provide options when modifying the holdings of existing licensees?[3]

What are the enforceable interference protection rights granted to licensed or registered receive-only earth station operators against co-primary terrestrial operations? What obligations does section 316 of the Act places on the Commission vis-à-vis licensed or registered receive-only earth station operators? Are registered receive-only earth station operators eligible to voluntarily relinquish their rights to protection from harmful interference in the reverse phase of an incentive auction because they qualify as ''licenses'' under § 309(j)(8)(G)? Does the Commission have other statutory authorities that would enable it to authorize payments to such earth stations to induce them to modify or relocate their facilities?

11. Receive-only earth stations cannot cause interference, but under the Commission's current rules they can be coordinated and licensed or registered with the Commission to protect them from terrestrial fixed services.[4] On April 19, 2018, the International Bureau temporarily waived the coordination requirement for earth station applications filed during a window that closed on October 31, 2018. Registrations or licenses granted for

[2] Consistent with the Commission's proposals in the *NPRM* for protecting incumbent earth stations that were operational as of April 19, 2018, for the questions in this document, the term ''registered receive-only earth station operators'' is intended to include applicants who had registration applications pending in IBFS as of the date the freeze exception filing window ended. Thus, the term would include applications that have not yet been processed by Federal Communications Commission staff, as well as applications without a showing of frequency coordination with terrestrial fixed service. *See NPRM,* 33 FCC Rcd at 6926, paragraph 27, 83 FR. at 44130.

[3] *See, e.g.,* 47 CFR 101.73(d), 101.75(b), 101.89(d) (comparable facilities defined in terms of throughput, reliability, and operating costs); *Improving Public Safety Communications in the 800 MHz Band* et al., *Report and Order, Fifth Report and Order, Fourth Memorandum Opinion and Order, and Order,* 19 FCC Rcd 14969, paragraph 68 (2004); *Use of Spectrum Bands Above 24 GHz For Mobile Radio Services, et al.,* GN Docket No. 14–177, *Fourth Report and Order,* FCC 18–180, at paragraph 15 (Dec. 12, 2018).

[4] 47 CFR 25.131(b) (filing requirements and registration for receive-only earth stations). Receive-only earth stations in the Fixed Satellite Service that operate with U.S.-licensed space stations, or with non-U.S.-licensed space stations that have been duly approved for U.S. market access, may be registered with the Commission in order to protect them from interference from terrestrial microwave stations in bands shared co-equally with the Fixed Service in accordance with the procedures of §§ 25.203 and 25.251, subject to the structure in § 25.209(c). Receive-only earth stations must be licensed in cases where they seek to operate with non-U.S.-licensed space stations that have not been approved for market access. *See* 47 CFR 25.131(j).

applications filed during the window without the coordination report will include a condition noting that the license or registration does not afford interference protection from fixed service transmissions. Upon announcing the termination of the freeze, the International Bureau may modify or terminate the waiver by requiring or permitting registrants or licensees who filed applications within the window without a coordination report to file such a report as required by the Commission's rules, and to take any appropriate action in light of such filing.

12. The *NPRM* proposed to protect incumbent earth stations from harmful interference as the Commission increased the intensity of terrestrial use in the band.[5] What is the scope of the right of such users to protection from harmful interference? What obligations, if any, does section 316 of the Communications Act (or any other provision of the Act) impose on the Commission vis-à-vis licensed or registered receive-only earth station operators if the Commission were to authorize new terrestrial operations in the band under any of the proposals in the *NPRM* or the record?

13. The Commission seeks comment on whether licensed or registered receive-only earth stations have licensed spectrum usage rights, as defined in the Communications Act of 1934, as amended (the Act). Section 309(j)(8)(G) of the Act, provides that the Commission ''may encourage a licensee to relinquish voluntarily some or all of its licensed spectrum usage rights'' as part of an incentive auction. This provision, however, does not define the term ''licensee'' or ''licensed spectrum usage rights.'' Section 3(53) of the Act defines ''license'' as ''that instrument of authorization required by [the Act] or the rules and regulations of the Commission made pursuant to [the Act], for the use or operation of apparatus for transmission of energy, or communications, or signals by radio, by whatever name the instrument may be designated by the Commission.'' The ''transmission of energy . . . by radio,'' in turn, is defined to include ''all instrumentalities, facilities, and services incidental to such transmission.'' In light of these and any other statutory provisions that may be relevant, how should the Commission interpret ''licensed spectrum usage rights'' as it may apply to any of the proposals either advanced by the Commission in the *NPRM* or raised in comments filed in this docket?

14. Receive-only earth stations do not transmit ''energy, or communications, or signals'' and most have not been eligible for a Commission license since 1991. However, in adopting the receive-only earth station registration program, the Commission provided that ''a registration program will afford the same protection from interference as would a license issued under our former [licensing] procedure.'' Do licensed or registered receive-only earth station operators meet the definition of licensees that have licensed spectrum usage rights that they could voluntarily relinquish in an incentive auction? Some commenters argue that registered earth stations have licensed spectrum usage rights, while other commenters argue that earth station registrations are not licenses under § 309(j)(8)(G). At least one commenter suggests that the Commission consider holding a reverse auction in which incumbent receive-only earth station registrants and satellite licensees would compete to submit winning bids to clear a PEA. Does the Commission's incentive auction authority allow it to structure a reverse auction in which satellite operators and licensed or registered receive-only earth station operators compete to relinquish their spectrum usage rights? What, if any, legal authority does the Commission have to structure an incentive auction that would award initial licenses for mobile operations in the band subject to protecting or reaching agreements with licensed or registered receive-only earth stations? For that matter, do non-U.S.-licensed space station operators granted market access meet the definition of licensees that have licensed spectrum usage rights that they could voluntarily relinquish in an incentive auction?

15. If an incentive auction approach is unavailable, does the Commission have other statutory authorities that would enable it to authorize or require payments to licensed or registered receive-only earth stations to induce them to modify or relocate their facilities? One commenter argues that §§ 303(c), 303(r), and 4(i) of the Act, and specific Commission precedent, provide the Commission with ample authority to require that proceeds from a Commission auction or a private sale of spectrum usage rights to be shared with registered receive-only earth stations as well as with the U.S. Treasury. Another commenter maintains that the Commission recognized the important role of receive-only earth stations in the *NPRM* when it asked whether, ''[i]nstead of paying [fixed satellite] operators for relinquishing spectrum usage rights nationwide, or in specific geographic regions, a mechanism instead might pay earth stations for relinquishing access to C-band spectrum in specific geographic areas.'' Are there any other rules or sources of authority the Commission should consider in addressing the question of how to accommodate licensed or registered earth station operators that may be displaced as a result of repurposing of the C-band? Are there any equitable or public policy factors the Commission should take into consideration?

Federal Communications Commission.

John Schauble,

Deputy Division Chief, Broadband Division, Wireless Telecommunication Bureau.

[FR Doc. 2019–11448 Filed 5–31–19; 8:45 am]

BILLING CODE 6712–01–P

[5] *See NPRM,* 33 FCC Rcd at 6926, paragraph 27, 83 FR. at 44130. The Commission sought comment on how to define the appropriate class of incumbents for protection. For earth station licensees and registrants, the *NPRM* proposed to define incumbent stations as earth stations that: (1) Were operational as of April 19, 2018; (2) are licensed or registered (or had a pending application for license or registration) in the IBFS database as of October 17, 2018; and (3) have timely certified the accuracy of information on file with the Commission to the extent required by the *Order. Id.* The filing deadline was subsequently extended until October 31, 2018. *International Bureau Announces Two-Week Extension of Filing Window for Earth Stations Currently Operating in 3.7–4.2 GHz Band, Public Notice,* 33 FCC Rcd 10054 (IB Oct. 17, 2018).

Notices

Federal Register

Vol. 84, No. 106

Monday, June 3, 2019

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

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

May 29, 2019.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by July 3, 2019 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725 17th Street NW, Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Food Safety and Inspection Service

Title: Importation and Transportation of Meat, Poultry and Egg Products.

OMB Control Number: 0583–0094.

Summary of Collection: The Food Safety and Inspection Service (FSIS) has been delegated the authority to exercise the functions of the Secretary as provided in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031, *et seq.*) These statutes mandate that FSIS protect the public by ensuring that meat, poultry, and egg products are safe, wholesome, unadulterated, and properly labeled and packaged. Meat and poultry products not marked with the mark of inspection and shipped from one official establishment to another for further processing must be transported under FSIS seal to prevent such unmarked product from' entering commerce. To track product shipped under seal, FSIS requires shipping establishments to complete a form that identifies the type, amount, and weight of the product. Foreign countries that wish to export meat, poultry, and egg products to the United States must establish eligibility to do so by putting in place inspection systems that are ''equivalent to'' the U.S. inspection system (9 CFR 327.2 and 381.196) and by annually certifying that they continue to do so.

Need and Use of the Information: FSIS will collect information using form 7350–1, Request and Notice of Shipment of Sealed Meat/Poultry. FSIS will collect the name, number, method of shipping, and destination of product, type and description of product to be shipped, reason for shipping product, and a signature. Meat, poultry, and egg products intended for importation into the U.S. must be accompanied by an inspection certificate signed by an official of the foreign government responsible for the inspection and certification of the product.

Description of Respondents: Business or other for-profit.

Number of Respondents: 136.

Frequency of Responses: Recordkeeping; Reporting: On occasion.

Total Burden Hours: 4,026.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2019–11469 Filed 5–31–19; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

Foreign Agricultural Service

Notice of Request for an Extension of a Currently Approved Information Collection

AGENCY: Commodity Credit Corporation and Foreign Agricultural Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Commodity Credit Corporation's (CCC) intention to request an extension for a currently approved information collection in support of the CCC Facility Guarantee Program (FGP).

DATES: Comments on this notice must be received by August 2, 2019 to be assured consideration.

FOR FURTHER INFORMATION CONTACT: Contact Amy Slusher, Deputy Director, Credit Program Division, Office of Trade Programs, Foreign Agricultural Service, U.S. Department of Agriculture, AgStop 1025, Washington, DC 20250–1025, telephone (202) 720–0775.

SUPPLEMENTARY INFORMATION:

Title: CCC Facility Guarantee Program (FGP).

OMB Number: 0551–0032.

Expiration Date of Approval: September 30, 2019.

Type of Request: Update of a currently approved information collection.

Abstract: Under the FGP, CCC provides payment guarantees to facilitate the financing of manufactured goods and U.S. services to improve or establish agriculture-related facilities in emerging markets. By supporting such facilities, the FGP is designed to enhance sales of U.S. agricultural commodities and products to emerging markets where the demand for such commodities and products may be

limited due to inadequate storage, processing, handling, or distribution capabilities for such products.

The FGP is currently available in 92 countries. Under 7 CFR part 1493, U.S. sellers, foreign banks, and U.S. banks are required to submit the following: (1) Information about the seller, foreign banks, and U.S. banks for program participation; (2) applications for payment guarantees; (3) environmental impact statement/assessment; (4) notice of assignment of payment guarantee; (5) evidence of performance; (6) notice of default and claims for loss; and (7) dispute resolution and appeals. In addition, each seller and seller's assignee (U.S. financial institution) must maintain records on all information submitted to CCC and in connection with sales made under FGP. The information collected is used by CCC to manage, plan, evaluate, and account for government resources. The reports and records are required to ensure the proper and judicious use of public funds.

Estimate of Burden: The public reporting burden for these collections is estimated to average 1.281 hours per response.

Respondents: U.S. exporters (sellers), U.S. financial institutions, and foreign financial institutions.

Estimated Number of Respondents: 18 per year.

Estimated Number of Responses per Respondent: 15.6 per year.

Estimated Total Annual Burden of Respondents: 360.5 hours.

Copies of this information collection can be obtained from Connie Ehrhart, the Agency Information Collection Coordinator, at (202) 690–1578 or email at *Connie.Ehrhart@fas.usda.gov*.

Request for Comments: Send comments regarding (a) 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) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent to Amy Slusher, Deputy Director, Credit Programs Division, Office of Trade Programs, Foreign Agricultural Service, U.S. Department of Agriculture, AgStop 1025, Washington, DC 20250–1025, or to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, DC 20503.

Persons with disabilities who require an alternative means for communication of information (Braille, large print, audiotape, etc.) should contact USDA's Target Center at (202) 720–2600 (voice and TDD). All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Dated: May 24, 2019.

Clay Hamilton,

Acting Administrator, Foreign Agricultural Service.

Dated: May 28, 2019.

Robert Stephenson,

Executive Vice President, Commodity Credit Corporation.

[FR Doc. 2019–11486 Filed 5–31–19; 8:45 am]

BILLING CODE 3410–10–P

BROADCASTING BOARD OF GOVERNORS

Sunshine Act Meetings

TIME AND DATE: Wednesday, June 5, 2019, 10:45 a.m. EDT.

PLACE: Cohen Building, Room 3321, 330 Independence Ave. SW, Washington, DC 20237.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED: The U.S. Agency for Global Media's (USAGM) Board of Governors (Board) will be meeting at the time and location listed above. The Board will vote on a consent agenda consisting of the minutes of its March 6, 2019 meeting, USAGM Social Media Policy, USAGM Smith-Mundt Guidelines, a resolution honoring the 65th anniversary of Radio Free Europe/Radio Liberty's Belarus Service, and a resolution honoring the 15th anniversary of the Middle East Broadcasting Networks' Alhurra Television and Alhurra-Iraq Television. The Board will receive a report from the USAGM's Chief Executive Officer and Director.

This meeting will be available for public observation via streamed webcast, both live and on-demand, on the agency's public website at *www.usagm.gov*. Information regarding this meeting, including any updates or adjustments to its starting time, can also be found on the agency's public website.

The public may also attend this meeting in person at the address listed above as seating capacity permits. Members of the public seeking to attend the meeting in person must register at *https://usagmboardmeetingjune2019.eventbrite.com* by 12:00 p.m. (ET) on June 4. For more information, please contact USAGM Public Affairs at (202) 203–4400 or by email at *pubaff@usagm.gov*.

CONTACT PERSON FOR MORE INFORMATION: Persons interested in obtaining more information should contact Oanh Tran at (202) 203–4545.

Oanh Tran,

Managing Director.

[FR Doc. 2019–11553 Filed 5–30–19; 11:15 am]

BILLING CODE 8610–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Massachusetts Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that a meeting of the Massachusetts Advisory Committee to the Commission will convene by conference call at 12:00 p.m. (EDT) on Thursday, June 13, 2019. The purpose of the meeting is to vote on the Advisory Memorandum on hate crimes.

DATES: Thursday, June 13, 2019, at 12:00 p.m. (EDT).

Public Call-In Information: Conference call-in number: 1–866–556–2485 and conference ID: 5633127.

FOR FURTHER INFORMATION CONTACT: Evelyn Bohor at *ero@usccr.gov* or by phone at 202–376–7533.

SUPPLEMENTARY INFORMATION: Interested members of the public may listen to the discussion by calling the following toll-free conference call-in number: 1–866–556–2485 and conference ID: 5633127. Please be advised that before placing them into the conference call, the conference call operator will ask callers to provide their names, their organizational affiliations (if any), and email addresses (so that callers may be notified of future meetings). Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free conference call-in number.

Persons with hearing impairments may also follow the discussion by first calling the Federal Relay Service at 1–800–877–8339 and providing the

operator with the toll-free conference call-in number: 1–866–556–2485 and conference ID: 5633127.

Members of the public are invited to make statements during the open comment period of the meeting or submit written comments. The comments must be received in the regional office approximately 30 days after each scheduled meeting. Written comments may be mailed to the Eastern Regional Office, U.S. Commission on Civil Rights, 1331 Pennsylvania Avenue, Suite 1150, Washington, DC 20425, faxed to (202) 376–7548, or emailed to Evelyn Bohor at *ero@usccr.gov*. Persons who desire additional information may contact the Eastern Regional Office at (202) 376–7533.

Records and documents discussed during the meeting will be available for public viewing as they become available at *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzllAAA,* click the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Eastern Regional Office, as they become available, both before and after the meetings. Persons interested in the work of this advisory committee are advised to go to the Commission's website, *www.usccr.gov,* or to contact the Eastern Regional Office at the above phone numbers, email or street address.

Agenda

Thursday, June 13, 2019 at 12:00 p.m. (EDT)

I. Roll Call
II. Vote on Hate Crimes Advisory Memorandum
III. Other Business
IV. Open Comment
VI. Adjournment

Dated: May 29, 2019.

David Mussatt,

Supervisory Chief, Regional Programs.

[FR Doc. 2019–11483 Filed 5–31–19; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the North Dakota Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that a briefing of the North Dakota Advisory Committee to the Commission will convene on Wednesday, June 19, 2019 at 12:00 p.m. (CDT) in the Stern Board Room of the Dakota Medical Foundation, 4141 28th Avenue, Fargo, ND 58104.The purpose of the briefing is to hear from advocates and public officials regarding hate crimes in North Dakota.

DATES: Wednesday, June 19, 2019, at 12:00 p.m. (CDT).

ADDRESSES: Stern Board Room, Dakota Medical Foundation, 4141 28th Avenue, Fargo, ND 58104.

Public Call Information: Dial: 1–800–667–5617, Conference ID: 5569765.

FOR FURTHER INFORMATION CONTACT: Evelyn Bohor, at *ebohor@usccr.gov* or by phone at 303–866–1040.

SUPPLEMENTARY INFORMATION: Members of the public may also listen to the discussion through the above listed toll free number. As well as attending in person, any interested member of the public may call the above listed number and listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Time will be set aside at the at the conclusion of the briefing so that members of the public may address the Committee after the formal presentations have been completed. Persons interested in the issue are also invited to submit written comments; the comments must be received in the regional office by Friday, July 19, 2019. Written comments may be mailed to the Rocky Mountain Regional Office, U.S. Commission on Civil Rights, 1961 Stout Street, Denver, CO 80294, faxed to (303) 866–1050, or emailed to Evelyn Bohor at *ero@usccr.gov*. Persons who desire additional information may contact the Rocky Mountain Regional Office at (303) 866–1040. Persons who plan to attend the briefing and require other accommodations, please contact Evelyn Bohor at ebohor@*usccr.gov* at the Rocky Mountain Regional Office at least ten (10) working days before the scheduled date of the meeting.

Records and documents discussed during the meeting will be available for public viewing as they become available at *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzl9AAA* and clicking on the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Western Regional Office, as they become available, both before and after the meeting. Persons interested in the work of this advisory committee are advised to go to the Commission's website, *www.usccr.gov,* or to contact the Rocky Mountain Regional Office at the above phone number, email or street address.

Agenda

Wednesday, June 19, 2019, at 12:00 p.m. (CDT)

I. Welcome and Introductions
II. Briefing on Hate Crimes
IV. Other Business
IV. Open Comment
IV. Adjournment

Dated: May 29, 2019.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2019–11482 Filed 5–31–19; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–8–2019]

Approval of Subzone Status; Hartland Controls, LLC; Rock Falls, Illinois

On February 4, 2019, the Executive Secretary of the Foreign-Trade Zones (FTZ) Board docketed an application submitted by the Jo-Carroll Foreign Trade Zone Board, grantee of FTZ 271, requesting subzone status subject to the existing activation limit of FTZ 271, on behalf of Hartland Controls, LLC, in Rock Falls, Illinois.

The application was processed in accordance with the FTZ Act and Regulations, including notice in the **Federal Register** inviting public comment (84 FR 2812, February 8, 2019). The FTZ staff examiner reviewed the application and determined that it meets the criteria for approval. Pursuant to the authority delegated to the FTZ Board Executive Secretary (15 CFR 400.36(f)), the application to establish

Subzone 271B was approved on May 28, 2019, subject to the FTZ Act and the Board's regulations, including Section 400.13, and further subject to FTZ 271's 2,000-acre activation limit.

Dated: May 28, 2019.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2019–11477 Filed 5–31–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–37–2019]

Foreign-Trade Zone (FTZ) 230—Piedmont Triad Area, North Carolina; Notification of Proposed Production Activity; MVP International Group, Inc.; (Candles, Reed Diffusers, Wax Melts); Elkin and Boonville, North Carolina

The Piedmont Triad Partnership, grantee of FTZ 230, submitted a notification of proposed production activity to the FTZ Board on behalf of MVP International Group, Inc. (MVP), located at sites in Elkin and Boonville, North Carolina. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on May 24, 2019.

The MVP facilities are located within Subzone 230G. The facilities are used for the production of candles, reed diffusers and wax melts. Pursuant to 15 CFR 400.14(b), FTZ activity would be limited to the specific foreign-status materials and components and specific finished products described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt MVP from customs duty payments on the foreign-status components used in export production. On its domestic sales, for the foreign-status materials/components noted below, MVP would be able to choose the duty rates during customs entry procedures that apply to candles, reed diffusers and wax melts (duty rate ranges from duty-free to 6%). MVP would be able to avoid duty on foreign-status components which become scrap/waste. Customs duties also could possibly be deferred or reduced on foreign-status production equipment.

The components and materials sourced from abroad include: Palm stearic; plastic lids; wooden bowls and vessels; plastic bottles, flasks and containers; glass candle holders; glass jars, bottles and containers; metal lids of tin, aluminum, and steel; wood lids; cement jars; cork lids; ceramic jars and containers; mineral oil; reed (rattan); ceramic bottles and containers; acetate packing; and, aromatic wax (duty rate ranges from duty-free to 30%).

The request indicates that certain materials/components are subject to special duties under Section 301 of the Trade Act of 1974 (Section 301), depending on the country of origin. The applicable Section 301 decisions require subject merchandise to be admitted to FTZs in privileged foreign status (19 CFR 146.41).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is July 15, 2019.

A copy of the notification will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230–0002, and in the ''Reading Room'' section of the Board's website, which is accessible via *www.trade.gov/ftz*.

For further information, contact Diane Finver at *Diane.Finver@trade.gov* or (202) 482–1367.

Dated: May 28, 2019.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2019–11478 Filed 5–31–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: Bureau of Industry and Security.

Title: Simple Network Application Process and Multipurpose Application Form.

Form Number(s): 748P, 748P–A, 748P–B.

OMB Control Number: 0694–0088.

Type of Request: Regular submission.

Estimated Total Burden Hours: 31,878 hours.

Estimated Number of Respondents: 64,616 respondents.

Estimated Time per Response: 49 minutes per response.

Needs and Uses: BIS administers a system of export and re-export controls in accordance with the EAR. In doing so, BIS requires that parties wishing to engage in certain transactions apply for licenses, submit Encryption Review Requests, or submit notifications to BIS through, the Simplified Network Application Process—Redesign (SNAP–R), the System for Tracking Export License Applications (STELA), the Multipurpose application Form BIS 748P and its two appendices 748P–A and 748P–B, or by submitting an Advisory Opinion request pursuant to the instructions in § 748.3(c) of the EAR.

Affected Public: Businesses and other for-profit institutions.

Frequency: On occasion.

Respondent's Obligation: Mandatory.

This information collection request may be viewed at *reginfo.gov http://www.reginfo.gov/public/*. 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*.

Sheleen Dumas,

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

[FR Doc. 2019–11456 Filed 5–31–19; 8:45 am]

BILLING CODE 3510–33–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.

Deadline for Particular Market Situation Allegation

Section 504 of the Trade Preferences Extension Act of 2015 amended the Act by adding the concept of particular market situation (PMS) for purposes of constructed value under section 773(e) of the Act.[1] Section 773(e) of the Act states that ''if a particular market situation exists such that the cost of materials and fabrication or other processing of any kind does not accurately reflect the cost of production in the ordinary course of trade, the administering authority may use another calculation methodology under this subtitle or any other calculation methodology.'' When an interested party submits a PMS allegation pursuant to section 773(e) of the Act, Commerce will respond to such a submission consistent with 19 CFR 351.301(c)(2)(v). If Commerce finds that a PMS exists under section 773(e) of the Act, then it will modify its dumping calculations appropriately.

Neither section 773(e) of the Act nor 19 CFR 351.301(c)(2)(v) set a deadline for the submission of PMS allegations and supporting factual information. However, in order to administer section 773(e) of the Act, Commerce must receive PMS allegations and supporting factual information with enough time to consider the submission. Thus, should an interested party wish to submit a PMS allegation and supporting new factual information pursuant to section 773(e) of the Act, it must do so no later than 20 days after submission of initial Section D responses.

Opportunity To Request a Review: Not later than the last day of June 2019,[2] interested parties may request administrative review of the following orders, findings, or suspended investigations, with anniversary dates in June for the following periods:

	Period of review
Antidumping Duty Proceedings	
GERMANY: Certain Cold-Drawn Mechanical Tubing of Carbon and Alloy Steel, A–428–845	11/22/17–5/31/19
INDIA: Certain Cold-Drawn Mechanical Tubing of Carbon and Alloy Steel, A–533–873	11/22/17–5/31/19
ITALY: Certain Cold-Drawn Mechanical Tubing of Carbon and Alloy Steel, A–475–838	11/22/17–5/31/19
JAPAN:	
Carbon and Alloy Seamless Standard, Line, and Pressure (over 4½ inches), A–588–850	6/1/18–5/31/19
Carbon and Alloy Seamless Standard, Line, and Pressure (under 4½ inches), A–588–851	6/1/18–5/31/19
MEXICO: Prestressed Concrete Steel Rail Tie Wire, A–201–843	6/1/18–5/31/19

[1] *See* Trade Preferences Extension Act of 2015, Public Law 114–27, 129 Stat. 362 (2015).

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

[3] Commerce inadvertently published the wrong period of review (POR) for Carton-Closing Staples in *Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 84 FR 18479 (May 1, 2019). The correct POR is listed above.

	Period of review
REPUBLIC OF KOREA: Certain Cold-Drawn Mechanical Tubing of Carbon and Alloy Steel, A–580–892	11/22/17–5/31/19
SOCIALIST REPUBLIC OF VIETNAM: Certain Tool Chests and Cabinets, A–552–821	11/16/17–5/31/19
SPAIN:	
Chlorinated Isocyanurates, A–469–814	6/1/18–5/31/19
Finished Carbon Steel Flanges, A–469–815	6/1/18–5/31/19
SWITZERLAND: Certain Cold-Drawn Mechanical Tubing of Carbon and Alloy Steel, A–441–801	11/22/17–5/31/19
TAIWAN: Helical Spring Lock Washers, A–583–820	6/1/18–5/31/19
THE PEOPLE'S REPUBLIC OF CHINA:	
Artist Canvas, A–570–899	6/1/18–5/31/19
Carton-Closing Staples,[3] A–570–055	11/3/17–4/30/19
Certain Cold-Drawn Mechanical Tubing of Carbon and Alloy Steel, A–570–058	11/22/17–5/31/19
Certain Tool Chests and Cabinets, A–570–056	11/16/17–5/31/19
Chlorinated Isocyanurates, A–570–898	6/1/18–5/31/19
Furfuryl Alcohol, A–570–835	6/1/18–5/31/19
High Pressure Steel Cylinders, A–570–977	6/1/18–5/31/19
Polyester Staple Fiber, A–570–905	6/1/18–5/31/19
Prestressed Concrete Steel Rail Tie Wire, A–570–990	6/1/18–5/31/19
Prestressed Concrete Steel Wire Strand, A–570–945	6/1/18–5/31/19
Silicon Metal, A–570–806	6/1/18–5/31/19
Tapered Roller Bearings, A–570–601	6/1/18–5/31/19
Countervailing Duty Proceedings	
THE PEOPLE'S REPUBLIC OF CHINA:	
High Pressure Steel Cylinders, C–570–978	1/1/18–12/31/18
Stainless Steel Flanges, C–570–065	1/23/18–12/31/18
Suspension Agreements	
None.	

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 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.[4]

Commerce no longer considers the non-market economy (NME) entity as an exporter conditionally subject to an antidumping duty administrative reviews.[5] 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.[6] 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

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

[5] *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).

[6] 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.

website at *http://access.trade.gov.*[7] 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 June 2019. If Commerce does not receive, by the last day of June 2019, 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: May 23, 2019.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2019–11480 Filed 5–31–19; 8:45 am]

BILLING CODE 3510–DS–P

[7] *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

[C–489–838, C–533–890]

Certain Quartz Surface Products From India and the Republic of Turkey: Initiation of Countervailing Duty Investigations

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

DATES: Applicable May 28, 2019.

FOR FURTHER INFORMATION CONTACT: Kristen Johnson at (202) 482–4793 (India) and Stephanie Berger at (202) 482–2483 (Republic of Turkey (Turkey)), AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

The Petitions

On May 8, 2019, the U.S. Department of Commerce (Commerce) received countervailing duty (CVD) petitions concerning imports of certain quartz surface products (quartz surface products) from India and Turkey, filed in proper form on behalf of Cambria Company LLC (the petitioner), a domestic producer of quartz surface products.[1] The Petitions were accompanied by antidumping duty (AD) petitions concerning imports of quartz surface products from India and Turkey.[2]

On May 10, May 13, and May 20, 2019, Commerce requested supplemental information pertaining to certain aspects of the Petitions in separate supplemental questionnaires.[3] The petitioner filed responses to the supplemental questionnaires on May 14, May 15, May 21, and May 24, 2019.[4]

In accordance with section 702(b)(1) of the Tariff Act of 1930, as amended (the Act), the petitioner alleges that the Governments of India and Turkey (GOI and GOT, respectively) are providing countervailable subsidies, within the meaning of sections 701 and 771(5) of the Act, to producers of quartz surface products in India and Turkey and that imports of such products are materially injuring, or threatening material injury to, the domestic quartz surface products industry in the United States. Consistent with section 702(b)(1) of the Act and 19 CFR 351.202(b), for those alleged programs on which we are initiating CVD investigations, the Petitions are accompanied by information reasonably available to the petitioner supporting their allegations.

Commerce finds that the petitioner filed the Petitions on behalf of the domestic industry, because the petitioner is an interested party, as defined in section 771(9)(C) of the Act. Commerce also finds that the petitioner demonstrated sufficient industry support necessary for the initiation of the requested CVD investigations.[5]

Periods of Investigation

Because the Petitions were filed on May 8, 2019, the periods of investigation (POI) are January 1, 2018, through December 31, 2018, or the most recently completed fiscal year for the foreign government and all of the companies under investigation, provided the foreign government and the companies have the same fiscal year.

Scope of the Investigations

The products covered by these investigations are quartz surface products from India and Turkey. For a full description of the scope of these investigations, *see* the Appendix to this notice.

Comments on the Scope of the Investigations

During our review of the Petitions, we contacted the petitioner regarding the proposed scope to ensure that the scope language in the Petitions is an accurate reflection of the products for which the domestic industry is seeking relief.[6] As a result, the scope of the Petitions was modified to clarify the description of the merchandise covered by the Petitions. The description of the merchandise covered by these investigations, as described in the Appendix to this notice, reflects these clarifications.

As discussed in the *Preamble* to Commerce's regulations, we are setting aside a period for interested parties to raise issues regarding product coverage

[1] *See* the petitioner's letter, ''Petitions for the Imposition of Antidumping and Countervailing Duties: Certain Quartz Surface Products from India and the Republic of Turkey,'' dated May 8, 2019 (the Petitions).

[2] *Id.*

[3] *See* Commerce's letters, ''Petition for the Imposition of Countervailing Duties on Imports of Certain Quartz Surface Products from India: Supplemental Questions,'' dated May 10, 2019; ''Petition for the Imposition of Countervailing Duties on Imports of Certain Quartz Surface Products from the Republic of Turkey: Supplemental Questions,'' dated May 10, 2019; ''Petitions for the Imposition of Antidumping and Countervailing Duties on Imports of Certain Quartz Surface Products from India and the Republic of Turkey: Supplemental Questions,'' dated May 13, 2019 (General Issues Supplemental); and Memorandum, ''Phone Call with Counsel to the Petitioner,'' dated May 20, 2019 (May 20, 2019 Memorandum).

[4] *See* the petitioner's letters, ''Quartz Surface Products from India: Response to Questionnaire,'' dated May 14, 2019; ''Quartz Surface Products from Turkey: Response to Questionnaire,'' dated May 14, 2019; ''Certain Quartz Surface Products from India and the Republic of Turkey: Response to General Issues Questionnaire,'' dated May 15, 2019 (General Issues Supplement); ''Certain Quartz Surface Products from India and the Republic of Turkey: Supplemental Response on Scope,'' dated May 21, 2019; and ''Certain Quartz Surface Products from India and the Republic of Turkey: Amendment to Petitions,'' dated May 24, 2019 (Third General Issues Supplement).

[5] *See* the ''Determination of Industry Support for the Petition'' section, *infra.*

[6] *See* General Issues Supplemental; *see also* May 20, 2019 Memorandum.

(scope).[7] Commerce will consider all comments received from interested parties and, if necessary, will consult with interested parties prior to the issuance of the preliminary determinations. If scope comments include factual information,[8] all such factual information should be limited to public information. To facilitate preparation of its questionnaires, Commerce requests that all interested parties submit such comments by 5:00 p.m. Eastern Time (ET) on June 17, 2019, which is 20 calendar days from the signature date of this notice. Any rebuttal comments, which may include factual information, must be filed by 5:00 p.m. ET on June 27, 2019, which is 10 calendar days from the initial comments deadline.[9]

Commerce requests that any factual information parties consider relevant to the scope of the investigations be submitted during this period. However, if a party subsequently finds that additional factual information pertaining to the scope of the investigations may be relevant, the party may contact Commerce and request permission to submit the additional information. All such submissions must be filed on the records of the concurrent AD and CVD investigations.

Filing Requirements

All submissions to Commerce must be filed electronically via Enforcement and Compliance's Antidumping Duty and Countervailing Duty Centralized Electronic Service System (ACCESS).[10] An electronically filed document must be received successfully in its entirety by the time and date it is due. Documents exempted from the electronic submission requirements must be filed manually (*i.e.,* in paper form) with Enforcement and Compliance's APO/Dockets Unit, Room 18022, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, and stamped with the date and time of receipt by the applicable deadlines.

Consultations

Pursuant to sections 702(b)(4)(A)(i) and (ii) of the Act, Commerce notified representatives of the GOI and GOT of the receipt of the Petitions and provided them the opportunity for consultations with respect to the Petitions.[11] Consultations were held with the GOI on May 21, 2019, and with the GOT on May 24, 2019.[12]

Determination of Industry Support for the Petitions

Section 702(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 702(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (i) At least 25 percent of the total production of the domestic like product; and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition. Moreover, section 702(c)(4)(D) of the Act provides that, if the petition does not establish support of domestic producers or workers accounting for more than 50 percent of the total production of the domestic like product, Commerce shall: (i) Poll the industry or rely on other information in order to determine if there is support for the petition, as required by subparagraph (A); or (ii) determine industry support using a statistically valid sampling method to poll the ''industry.''

Section 771(4)(A) of the Act defines the ''industry'' as the producers, as a whole, of a domestic like product. Thus, to determine whether a petition has the requisite industry support, the statute directs Commerce to look to producers and workers who produce the domestic like product. The International Trade Commission (ITC), which is responsible for determining whether ''the domestic industry'' has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both Commerce and the ITC must apply the same statutory definition regarding the domestic like product,[13] they do so for different purposes and pursuant to a separate and distinct authority. In addition, Commerce's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to law.[14]

Section 771(10) of the Act defines the domestic like product as ''a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title.'' Thus, the reference point from which the domestic like product analysis begins is ''the article subject to an investigation'' (*i.e.,* the class or kind of merchandise to be investigated, which normally will be the scope as defined in the petition).

With regard to the domestic like product, the petitioner does not offer a definition of the domestic like product distinct from the scope of the investigations.[15] Based on our analysis of the information submitted on the record, we have determined that quartz surface products, as defined in the scope, constitute a single domestic like product, and we have analyzed industry support in terms of that domestic like product.[16]

In determining whether the petitioner has standing under section 702(c)(4)(A) of the Act, we considered the industry support data contained in the Petitions with reference to the domestic like product as defined in the ''Scope of the Investigations,'' in the Appendix to this notice. To establish industry support, the petitioner provided its own production of the domestic like product

[7] *See Antidumping Duties; Countervailing Duties; Final Rule,* 62 FR 27296, 27323 (May 19, 1997) (*Preamble*).

[8] *See* 19 CFR 351.102(b) (21) (defining ''factual information'').

[9] *See* 19 CFR 351.303(b).

[10] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011); *see also Enforcement and Compliance: Change of Electronic Filing System Name,* 79 FR 69046 (November 20, 2014) for details of Commerce's electronic filing requirements, which went into effect on August 5, 2011. Information on help using ACCESS can be found at *https://access.trade.gov/help.aspx,* and a handbook can be found at *https://access.trade.gov/help/Handbook%20on%20Electronic%20Filling%20Procedures.pdf.*

[11] *See* Commerce's letters, ''Countervailing Duty Petition on Certain Quartz Surface Products from India: Invitation for Consultations to Discuss the Countervailing Duty Petition,'' dated May 9, 2019, and ''Countervailing Duty Petition on Certain Quartz Surface Products from Turkey: Invitation for Consultations to Discuss the Countervailing Duty Petition,'' dated May 9, 2019.

[12] *See* Memoranda, ''Consultations with Government of India Officials regarding the Countervailing Duty Petition on Certain Quartz Surface Products from India,'' dated May 21, 2019; and ''Consultations with Government of Turkey Officials regarding the Countervailing Duty Petition on Certain Quartz Surface Products from the Republic of Turkey,'' dated May 24, 2019.

[13] *See* section 771(10) of the Act.

[14] *See USEC, Inc.* v. *United States,* 132 F. Supp. 2d 1, 8 (CIT 2001) (citing *Algoma Steel Corp., Ltd.* v. *United States,* 688 F. Supp. 639, 644 (CIT 1988), *aff'd* 865 F.2d 240 (Fed. Cir. 1989)).

[15] *See* Volume I of the Petitions, at 8–11 and Exhibit I–6; *see also* General Issues Supplement at 2–4.

[16] For a discussion of the domestic like product analysis as applied to these cases and information regarding industry support, *see* Countervailing Duty Investigation Initiation Checklist: Certain Quartz Surface Products from India (India CVD Initiation Checklist), at Attachment II; *see also* Analysis of Industry Support for the Antidumping and Countervailing Duty Petition Covering Quartz Surface Products from India and the Republic of Turkey (Attachment II); and Countervailing Duty Investigation Initiation Checklist: Certain Quartz Surface Products from the Republic of Turkey (Turkey CVD Initiation Checklist), at Attachment II. These checklists are dated concurrently with this notice and on file electronically via ACCESS. Access to documents filed via ACCESS is also available in the Central Records Unit, Room B8024 of the main Department of Commerce building.

in 2018 and compared this to the estimated total production of the domestic like product for the entire domestic industry.[17] We relied on data provided by the petitioner for purposes of measuring industry support.[18]

On May 24, 2019, we received comments on industry support from M S International, Inc. (MSI), a U.S. importer of quartz surface products from India and Turkey.[19] The petitioner responded to the industry support comments from MSI on May 28, 2019.[20] On May 28, 2019, we received comments from MSI, Bedrosians Tile & Stone, and Arizona Tile LLC, each of whom is a U.S. importer of quartz surface products from India and Turkey, pertaining to the timing of the petitioner's May 24, 2019 supplemental response.[21]

Our review of the data provided in the Petitions, the General Issues Supplement, the Third General Issues Supplement, the Petitioner's Letter, and other information readily available to Commerce indicates that the petitioner has established industry support for the Petitions.[22] With respect to the India Petition, the domestic producers (or workers) have met the statutory criteria for industry support under section 702(c)(4)(A)(i) of the Act because the domestic producers (or workers) who support the India Petition account for at least 25 percent of the total production of the domestic like product.[23] The India Petition also established support from domestic producers (or workers) accounting for more than 50 percent of the total production of the domestic like product and, as such, Commerce is not required to take further action in order to evaluate industry support (*e.g.,* polling or reliance on other information).[24] Finally, the domestic producers (or workers) have met the statutory criteria for industry support under section 702(c)(4)(A)(ii) of the Act because the domestic producers (or workers) who support the India Petition account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the India Petition.[25] Accordingly, Commerce determines that the India Petition was filed on behalf of the domestic industry, within the meaning of section 702(b)(1) of the Act.[26]

With respect to the Turkey Petition, the domestic producers (or workers) have also met the statutory criteria for industry support under section 702(c)(4)(A)(i) of the Act because the domestic producers (or workers) who support the Turkey Petition account for at least 25 percent of total production of the domestic like product.[27] The Turkey Petition did not establish support from domestic producers (or workers) accounting for more than 50 percent of the total production of the domestic like product, however, and Commerce was required to further evaluate industry support.[28] In this case, Commerce was able to rely on other information provided by the petitioner on the record, in accordance with sections 702(c)(4)(D)(i) and 702(c)(4)(A)(ii) of the Act, to determine industry support.[29] Based on information provided in the Turkey Petition, the domestic producers (or workers) have met the statutory criteria for industry support under section 702(c)(4)(A)(ii) of the Act because the domestic producers (or workers) who support the Turkey Petition account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the Turkey Petition.[30] Accordingly, Commerce determines that the Turkey Petition was filed on behalf of the domestic industry within the meaning of section 702(b)(1) of the Act.[31]

Injury Test

Because India and Turkey are ''Subsidies Agreement Countries'' within the meaning of section 701(b) of the Act, section 701(a)(2) of the Act applies to these investigations. Accordingly, the ITC must determine whether imports of the subject merchandise from India and/or Turkey materially injure, or threaten material injury to, a U.S. industry.

Allegations and Evidence of Material Injury and Causation

The petitioner alleges that imports of the subject merchandise are benefitting from countervailable subsidies and that such imports are causing, or threaten to cause, material injury to the U.S. industry producing the domestic like product. In addition, the petitioner alleges that subject imports exceed the negligibility threshold provided for under section 771(24)(A) of the Act.[32] In CVD petitions, section 771(24)(B) of the Act provides that imports of subject merchandise from developing and least developed countries must exceed the negligibility threshold of four percent. The petitioner also demonstrates that subject imports from India, which has been designated as a least developed country under section 771(36)(B) of the Act, exceed the negligibility threshold of four percent.[33]

The petitioner contends that the industry's injured condition is illustrated by a significant and increasing volume of subject imports; reduced market share; underselling and price depression or suppression; lost sales and revenues; and a decline in the domestic industry's employment variables and financial performance.[34] We have assessed the allegations and supporting evidence regarding material injury, threat of material injury, causation, as well as cumulation, and we have determined that these allegations are properly supported by adequate evidence, and meet the statutory requirements for initiation.[35]

[17] *See* Volume I of the Petitions, at 2–4 and Exhibits I–3 and I–4; *see also* General Issues Supplement, at 8–9 and Exhibits 10 and 11; Third General Issues Supplement, at 3 and Exhibits 1 and 2.

[18] *See* Volume I of the Petitions, at 2–4 and Exhibits I–3 and I–4; *see also* General Issues Supplement, at 8–9 and Exhibits 10 and 11; Third General Issues Supplement, at 3 and Exhibits 1 and 2. For further discussion, *see* India CVD Initiation Checklist, at Attachment II; and Turkey CVD Initiation Checklist, at Attachment II.

[19] *See* MSI's letter, ''Quartz Surface Products from India and the Republic of Turkey: Comments on the Lack of Standing of the Petitioner and Requests for Action,'' dated March 20, 2019 (MSI's Letter).

[20] *See* the petitioner's letter, ''Certain Quartz Surface Products from India and the Republic of Turkey: Petitioner's Response to MSI's Comments on Standing,'' dated May 28, 2019 (Petitioner's Letter).

[21] *See* letter from MSI, Bedrosians Tile & Stone, and Arizona Tile LLC, ''Quartz Surface Products from India and the Republic of Turkey: Preliminary Comments on Petitioner's Tardy Amendment to its Petitions,'' dated May 28, 2019 (Petition Amendment Comments).

[22] *See* India CVD Initiation Checklist, at Attachment II; *see also* Turkey CVD Initiation Checklist, at Attachment II.

[23] *See* India CVD Initiation Checklist, at Attachment II.

[24] *See id.; see also* section 702(c)(4)(D) of the Act.

[25] *See* India CVD Initiation Checklist, at Attachment II

[26] *Id.*

[27] *See* Turkey CVD Initiation Checklist, at Attachment II.

[28] *See* section 702(c)(4)(D) of the Act; *see also* Turkey CVD Initiation Checklist, at Attachment II.

[29] *See* Turkey CVD Initiation Checklist, at Attachment II.

[30] *Id.*

[31] *Id.*

[32] *See* Volume I of the Petitions, at 19 and Exhibit I–13; *see also* General Issues Supplement, at 10 and Exhibit 13.

[33] *See* Volume I of the Petitions, at 19 and Exhibit I–13; *see also* General Issues Supplement, at 10 and Exhibit 13.

[34] *See* Volume I of the Petitions, at 13, 15–40 and Exhibits I–3, I–10, I–13 through I–30; *see also* General Issues Supplement, at 10–14 and Exhibits 12 and 13.

[35] *See* India CVD Initiation Checklist, at Attachment III, Analysis of Allegations and Evidence of Material Injury and Causation for the Antidumping and Countervailing Duty Petitions Covering Certain Quartz Surface Products from India and the Republic of Turkey (Attachment III); *see also* Turkey CVD Initiation Checklist, at Attachment III.

Initiation of CVD Investigations

Based on the examination of the Petitions and supplemental responses, we find that they meet the requirements of section 702 of the Act. Therefore, we are initiating CVD investigations to determine whether imports of quartz surface products from India and Turkey benefit from countervailable subsidies conferred by the GOI and GOT. In accordance with section 703(b)(1) of the Act and 19 CFR 351.205(b)(1), unless postponed, we will make our preliminary determinations no later than 65 days after the date of this initiation.

India

Based on our review of the Petition for India, we find that there is sufficient information to initiate a CVD investigation on 34 of the 35 alleged programs. For a full discussion of the basis for our decision to initiate (or not initiate) on each program, *see* India CVD Initiation Checklist. A public version of the initiation checklist for this investigation is available on ACCESS.

Turkey

Based on our review of the Petition for Turkey, we find that there is sufficient information to initiate a CVD investigation on 17 of the 23 alleged programs. The petitioner alleged two programs, which we plan to examine as a single program in this investigation. For a full discussion of the basis for our decision to initiate (or not initiate) on each program, *see* Turkey CVD Initiation Checklist. A public version of the initiation checklist for this investigation is available on ACCESS.

Respondent Selection

In the Petitions, the petitioner named 92 companies in India and 25 companies in Turkey as producers/exporters of quartz surface products.[36] Commerce intends to follow its standard practice in CVD investigations and calculate company-specific subsidy rates in these investigations. In the event Commerce determines that the number of companies is large, and it cannot individually examine each company based upon Commerce's resources, where appropriate, Commerce intends to select mandatory respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports of quartz surface products from India and Turkey during the POI under the appropriate Harmonized Tariff Schedule of the United States numbers listed in the ''Scope of the Investigations,'' in the Appendix.

On May 22, 2019, Commerce released CBP data under Administrative Protective Order (APO) to all parties with access to information protected by APO and indicated that interested parties wishing to comment regarding the CBP data and respondent selection must do so within three business days of the publication date of the notice of initiation of these CVD investigations.[37] Commerce will not accept rebuttal comments regarding the CBP data or respondent selection.

Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305(b). Instructions for filing such applications may be found on the Commerce's website at *http://enforcement.trade.gov/apo*.

Comments must be filed electronically using ACCESS. An electronically filed document must be received successfully, in its entirety, by ACCESS no later than 5:00 p.m. ET on the date noted above. We intend to finalize our decisions regarding respondent selection within 20 days of publication of this notice.

Distribution of Copies of the Petitions

In accordance with section 702(b)(4)(A)(i) of the Act and 19 CFR 351.202(f), copies of the public version of the Petitions have been provided to the GOI and GOT via ACCESS. To the extent practicable, we will attempt to provide a copy of the public version of the Petitions to each exporter named in the Petitions, as provided under 19 CFR 351.203(c)(2).

ITC Notification

We will notify the ITC of our initiation, as required by section 702(d) of the Act.

Preliminary Determinations by the ITC

The ITC will preliminarily determine, within 45 days after the date on which the Petitions were filed, whether there is a reasonable indication that imports of quartz surface products from India and Turkey are materially injuring, or threatening material injury to, a U.S. industry.[38] A negative ITC determination in any country will result in the investigations being terminated with respect to that country.[39] Otherwise, these CVD investigations will proceed according to statutory and regulatory time limits.

Submission of Factual Information

Factual information is defined in 19 CFR 351.102(b)(21) as: (i) Evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by Commerce; and (v) evidence other than factual information described in (i)–(iv). Section 19 CFR 351.301(b) requires any party, when submitting factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted[40] and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct.[41] Time limits for the submission of factual information are addressed in 19 CFR 351.301, which provides specific time limits based on the type of factual information being submitted. Interested parties should review the regulations prior to submitting factual information in these investigations.

Extensions of Time Limits

Parties may request an extension of time limits before the expiration of a time limit established under 19 CFR 351.301, or as otherwise specified by the Secretary. In general, an extension request will be considered untimely if it is filed after the expiration of the time limit established under 19 CFR 351.301. For submissions that are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. ET on the due date. Under certain circumstances, we may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, we will inform parties in the letter or memorandum setting forth the deadline (including a specified time) by which extension requests must be filed to be considered timely. An extension request must be made in a separate, stand-alone submission; under

[36] *See* Volume I of the Petitions, at Exhibit I–9.

[37] *See* Memoranda, ''Countervailing Duty Petition of Certain Quartz Surface Products from India: Release of Customs Data from U.S. Customs and Border Protection,'' dated May 22, 2019, and ''Countervailing Duty Petition of Certain Quartz Surface Products from the Republic of Turkey: Release of Customs Data from U.S. Customs and Border Protection,'' dated May 22, 2019.

[38] *See* section 703(a)(2) of the Act.

[39] *See* section 703(a)(1) of the Act.

[40] *See* 19 CFR 351.301(b).

[41] *See* 19 CFR 351.301(b)(2).

limited circumstances we will grant untimely-filed requests for the extension of time limits. Parties should review *Extension of Time Limits; Final Rule,* 78 FR 57790 (September 20, 2013), available at *http://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm,* prior to submitting factual information in these investigations.

Certification Requirements

Any party submitting factual information in an AD or CVD proceeding must certify to the accuracy and completeness of that information.[42] Parties must use the certification formats provided in 19 CFR 351.303(g).[43] Commerce intends to reject factual submissions if the submitting party does not comply with the applicable certification requirements.

Notification to Interested Parties

Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305. On January 22, 2008, Commerce published *Antidumping and Countervailing Duty Proceedings: Documents Submission Procedures; APO Procedures,* 73 FR 3634 (January 22, 2008). Parties wishing to participate in these investigations should ensure that they meet the requirements of these procedures (*e.g.,* the filing of letters of appearance as discussed at 19 CFR 351.103(d)).

This notice is issued and published pursuant to sections 702(c)(2) and 777(i) of the Act and 19 CFR 351.203(c).

Dated: May 28, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix

Scope of the Investigations

The merchandise covered by the investigations is certain quartz surface products. Quartz surface products consist of slabs and other surfaces created from a mixture of materials that includes predominately silica (*e.g.,* quartz, quartz powder, cristobalite, glass powder) as well as a resin binder (*e.g.,* an unsaturated polyester). The incorporation of other materials, including, but not limited to, pigments, cement, or other additives does not remove the merchandise from the scope of the investigations. However, the scope of the investigations only includes products where the silica content is greater than any other single material, by actual weight. Quartz surface products are typically sold as rectangular slabs with a total surface area of approximately 45 to 60 square feet and a nominal thickness of one, two, or three centimeters. However, the scope of these investigations includes surface products of all other sizes, thicknesses, and shapes. In addition to slabs, the scope of these investigations includes, but is not limited to, other surfaces such as countertops, backsplashes, vanity tops, bar tops, work tops, tabletops, flooring, wall facing, shower surrounds, fire place surrounds, mantels, and tiles. Certain quartz surface products are covered by the investigations whether polished or unpolished, cut or uncut, fabricated or not fabricated, cured or uncured, edged or not edged, finished or unfinished, thermoformed or not thermoformed, packaged or unpackaged, and regardless of the type of surface finish.

In addition, quartz surface products are covered by the investigations whether or not they are imported attached to, or in conjunction with, non-subject merchandise such as sinks, sink bowls, vanities, cabinets, and furniture. If quartz surface products are imported attached to, or in conjunction with, such non-subject merchandise, only the quartz surface product is covered by the scope.

Subject merchandise includes material matching the above description that has been finished, packaged, or otherwise fabricated in a third country, including by cutting, polishing, curing, edging, thermoforming, attaching to, or packaging with another product, or any other finishing, packaging, or fabrication that would not otherwise remove the merchandise from the scope of the investigations if performed in the country of manufacture of the quartz surface products.

The scope of the investigations does not cover quarried stone surface products, such as granite, marble, soapstone, or quartzite. Specifically excluded from the scope of the investigations are crushed glass surface products. Crushed glass surface products must meet each of the following criteria to qualify for this exclusion: (1) The crushed glass content is greater than any other single material, by actual weight; (2) there are pieces of crushed glass visible across the surface of the product; (3) at least some of the individual pieces of crushed glass that are visible across the surface are larger than 1 centimeter wide as measured at their widest cross-section (''Glass Pieces''); and (4) the distance between any single Glass Piece and the closest separate Glass Piece does not exceed three inches.

The products subject to the scope are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under the following subheading: 6810.99.0010. Subject merchandise may also enter under subheadings 6810.11.0010, 6810.11.0070, 6810.19.1200, 6810.19.1400, 6810.19.5000, 6810.91.0000, 6810.99.0080, 6815.99.4070, 2506.10.0010, 2506.10.0050, 2506.20.0010, 2506.20.0080, and 7016.90.1050. The HTSUS subheadings set forth above are provided for convenience and U.S. Customs purposes only. The written description of the scope is dispositive.

[FR Doc. 2019–11487 Filed 5–31–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

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

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 July 2019

Pursuant to section 751(c) of the Act, the following Sunset Reviews are scheduled for initiation in July 2019 and will appear in that month's *Notice of Initiation of Five-Year (Sunset) Reviews* (Sunset Reviews).

	Department contact
Antidumping Duty Proceedings	
Malleable Cast Iron Pipe Fittings from China (A–570–881) (3rd Review)	Joshua Poole; (202) 482–1293.
Steel Threaded Rod from China (A–570–932) (2nd Review)	Matthew Renkey; (202) 482–2312.
Polyethylene Terephthalate from India (A–533–824) (3rd Review)	Jacqueline Arrowsmith; (202) 482–5255.
Polyethylene Terephthalate from Taiwan (A–583–837) (3rd Review)	Jacqueline Arrowsmith; (202) 482–5255.

[42] *See* section 782(b) of the Act.

[43] *See Certification of Factual Information to Import Administration During Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) (*Final Rule*); *see also* frequently asked questions regarding the *Final Rule,* available at *http://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.*

	Department contact
Countervailing Duty Proceedings	
Polyethylene Terephthalate from India (C–533–825) (3rd Review)	Jacqueline Arrowsmith; (202) 482–5255.

Suspended Investigations

No sunset reviews of suspended investigations are scheduled for initiation in July 2019.

Commerce's procedures for the conduct of Sunset Reviews are set forth in 19 CFR 351.218. The *Notice of Initiation of Five-Year (Sunset) Reviews* provides further information regarding what is required of all parties to participate in a 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 a 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: May 22, 2019.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2019–11481 Filed 5–31–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Advisory Committee on Supply Chain Competitiveness: Notice of Public Meetings

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

ACTION: Notice of open meetings.

SUMMARY: This notice sets forth the schedule and proposed topics of discussion for upcoming public meetings of the Advisory Committee on Supply Chain Competitiveness (Committee).

DATES: The meetings will be held on June 19, 2019, from 12:00 p.m. to 3:00 p.m., and June 20, 2019, from 9:00 a.m. to 4:00 p.m., Eastern Daylight Time (EDT).

ADDRESSES: The meetings will be held at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Research Library (Room 1894), Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Richard Boll, Office of Supply Chain, Professional & Business Services (OSCPBS), International Trade Administration. Phone: (202) 482–1135 or email: *richard.boll@trade.gov*.

SUPPLEMENTARY INFORMATION:

Background: The Committee was established under the discretionary authority of the Secretary of Commerce and in accordance with the Federal Advisory Committee Act (5 U.S.C. App.). It provides advice to the Secretary of Commerce on the necessary elements of a comprehensive policy approach to supply chain competitiveness and on regulatory policies and programs and investment priorities that affect the competitiveness of U.S. supply chains. For more information about the Committee visit: *http://trade.gov/td/services/oscpb/supplychain/acscc/*.

Matters To Be Considered: Committee members are expected to continue to discuss the major competitiveness-related topics raised at the previous Committee meetings, including trade and competitiveness; freight movement and policy; trade innovation; regulatory issues; finance and infrastructure; and workforce development. The Committee's subcommittees will report on the status of their work regarding these topics. The agenda may change to accommodate other Committee business. The Office of Supply Chain, Professional & Business Services will post the final detailed agendas on its website, *http://trade.gov/td/services/oscpb/supplychain/acscc/,* at least one week prior to the meeting.

The meetings will be open to the public and press on a first-come, first-served basis. Space is limited. The public meetings are physically accessible to people with disabilities. Individuals requiring accommodations, such as sign language interpretation or other ancillary aids, are asked to notify Richard Boll, at (202) 482–1135 or *richard.boll@trade.gov,* five (5) business days before the meeting.

Interested parties may submit written comments to the Committee at any time before and after the meeting. Parties wishing to submit written comments for consideration by the Committee in advance of this meeting must send them to the Office of Supply Chain, Professional & Business Services, 1401 Constitution Ave NW, Room 11014, Washington, DC 20230, or email to *richard.boll@trade.gov*.

For consideration during the meetings, and to ensure transmission to the Committee prior to the meetings, comments must be received no later than 5:00 p.m. EST on June 10, 2019. Comments received after June 10, 2019, will be distributed to the Committee, but may not be considered at the meetings. The minutes of the meetings will be posted on the Committee website within 60 days of the meeting.

Dated: May 29, 2019.

Maureen Smith,

Director, Office of Supply Chain.

[FR Doc. 2019–11504 Filed 5–31–19; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–489–837, A–533–889]

Certain Quartz Surface Products From India and the Republic of Turkey: Initiation of Less-Than-Fair-Value Investigations

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

DATES: Applicable May 28, 2019.

FOR FURTHER INFORMATION CONTACT: Kyle Clahane at (202) 482–5449 or Laurel LaCivita at (202) 482–4243 (Republic of Turkey (Turkey)); Keith Haynes (202) 482–5139 (India); AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

The Petitions

On May 8, 2019, the U.S. Department of Commerce (Commerce) received antidumping duty (AD) petitions concerning imports of certain quartz

surface products (quartz surface products) from India and Turkey, filed in proper form by Cambria Company LLC (the petitioner), a domestic producer of quartz surface products.[1] The Petitions were accompanied by countervailing duty (CVD) petitions concerning imports of quartz surface products from India and Turkey.[2]

On May 13, May 14, and May 20, 2019, Commerce requested supplemental information pertaining to certain aspects of the Petitions in separate supplemental questionnaires.[3] The petitioner filed responses to the supplemental questionnaires on May 15, May 16, May 21, and May 24, 2019.[4]

In accordance with section 732(b) of the Tariff Act of 1930, as amended (the Act), the petitioner alleges that imports of quartz surface products from India and Turkey are being, or are likely to be, sold in the United States at less than fair value (LTFV) within the meaning of section 731 of the Act, and that such imports are materially injuring, or threatening material injury to, the domestic industry producing quartz surface products in the United States. Consistent with section 732(b)(1) of the Act, the Petitions are accompanied by information reasonably available to the petitioner supporting its allegations.

Commerce finds that the petitioner filed the Petitions on behalf of the domestic industry, because the petitioner is an interested party, as defined in section 771(9)(C) of the Act. Commerce also finds that the petitioner demonstrated sufficient industry support with respect to the initiation of the requested AD investigations.[5]

Periods of Investigation

Because the Petitions were filed on May 8, 2019, the periods of investigation (POI) for the India and Turkey AD investigations is April 1, 2018, through March 31, 2019, pursuant to 19 CFR 351.204(b)(1).[6]

Scope of the Investigations

The products covered by these investigations are quartz surface products from India and Turkey. For a full description of the scope of these investigations, *see* the Appendix to this notice.

Comments on the Scope of the Investigations

During our review of the Petitions, we contacted the petitioner regarding the proposed scope to ensure that the scope language in the Petitions is an accurate reflection of the products for which the domestic industry is seeking relief.[7] As a result, the scope of the Petitions was modified to clarify the description of the merchandise covered by the Petitions. The description of the merchandise covered by these investigations, as described in the Appendix to this notice, reflects these clarifications.

As discussed in the *Preamble* to Commerce's regulations, we are setting aside a period for interested parties to raise issues regarding product coverage (scope).[8] Commerce will consider all comments received from interested parties and, if necessary, will consult with interested parties prior to the issuance of the preliminary determinations. If scope comments include factual information,[9] all such factual information should be limited to public information. To facilitate preparation of its questionnaires, Commerce requests that all interested parties submit scope comments by 5:00 p.m. Eastern Time (ET) on June 17, 2019, which is 20 calendar days from the signature date of this notice. Any rebuttal comments, which may include factual information, must be filed by 5:00 p.m. ET on June 27, 2019, which is 10 calendar days from the initial comment deadline.[10]

Commerce requests that any factual information parties consider relevant to the scope of the investigations be submitted during this period. However, if a party subsequently finds that additional factual information pertaining to the scope of the investigations may be relevant, the party may contact Commerce and request permission to submit the additional information. All such submissions must be filed on the records of the concurrent AD and CVD investigations.

Filing Requirements

All submissions to Commerce must be filed electronically via Enforcement and Compliance's Antidumping Duty and Countervailing Duty Centralized Electronic Service System (ACCESS).[11] An electronically filed document must be received successfully in its entirety by the time and date it is due. Documents exempted from the electronic submission requirements must be filed manually (*i.e.,* in paper form) with Enforcement and Compliance's APO/Dockets Unit, Room 18022, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, and stamped with the date and time of receipt by the applicable deadlines.

Comments on Product Characteristics

Commerce is providing interested parties an opportunity to comment on the appropriate physical characteristics of quartz surface products to be reported in response to Commerce's AD questionnaires. This information will be used to identify the key physical characteristics of the subject merchandise in order to report the relevant costs of production accurately, as well as to develop appropriate product-comparison criteria.

Interested parties may provide any information or comments that they feel are relevant to the development of an accurate list of physical characteristics.

[1] *See* the petitioner's letter, ''Petitions for the Imposition of Antidumping and Countervailing Duties: Certain Quartz Surface Products from India and the Republic of Turkey,'' dated May 8, 2019 (the Petitions).

[2] *Id.*

[3] *See* Commerce's letters, ''Petitions for the Imposition of Antidumping and Countervailing Duties on Imports of Certain Quartz Surface Products from India and the Republic of Turkey: Supplemental Questions,'' dated May 13, 2019 (General Issues Supplemental); ''Petition for the Imposition of Antidumping Duties on Imports of Certain Quartz Surface Products from India: Supplemental Questions,'' dated May 13, 2019 (India Supplemental); ''Petitions for the Imposition of Antidumping and Countervailing Duties on Imports of Certain Quartz Surface Products from India and the Republic of Turkey: Supplemental Questions,'' dated May 14, 2019 (Turkey Supplemental); and, Memorandum, ''Phone Call with Counsel to the Petitioner,'' dated May 20, 2019 (May 20, 2019 Memorandum).

[4] *See* the petitioner's letters, ''Certain Quartz Surface Products from India and the Republic of Turkey: Response to General Issues Questionnaire,'' dated May 15, 2019 (General Issues Supplement); ''Quartz Surface Products from Turkey: Response to Questionnaire on Antidumping Petition,'' dated May 16, 2019 (Turkey AD Supplement); ''Quartz Surface Products from India: Response to Questionnaire on Antidumping Petition,'' dated May 15, 2019 (India AD Supplement); ''Quartz Surface Products from India: Additional Response to Questionnaire on Antidumping Petition,'' dated May 21, 2019 (Second India AD Supplement); ''Certain Quartz Surface Products from India and the Republic of Turkey: Supplemental Response on Scope,'' dated May 21, 2019 (Second General Issues Supplement); and ''Certain Quartz Surface Products from India and the Republic of Turkey: Amendment to Petitions,'' dated May 24, 2019 (Third General Issues Supplement).

[5] *See* the ''Determination of Industry Support for the Petition'' section, *infra.*

[6] *See* 19 CFR 351.204(b)(1).

[7] *See* General Issues Supplemental; *see also* May 20, 2019 Memorandum.

[8] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997) (*Preamble*).

[9] *See* 19 CFR 351.102(b)(21) (defining ''factual information'').

[10] *See* 19 CFR 351.303(b).

[11] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011); *see also Enforcement and Compliance; Change of Electronic Filing System Name,* 79 FR 69046 (November 20, 2014) for details of Commerce's electronic filing requirements, effective August 5, 2011. Information on help using ACCESS can be found at *https://access.trade.gov/help.aspx* and a handbook can be found at *https://access.trade.gov/help/Handbook%20on%20Electronic%20Filling%20Procedures.pdf.*

Specifically, they may provide comments as to which characteristics are appropriate to use as: (1) General product characteristics, and (2) product comparison criteria. We note that it is not always appropriate to use all product characteristics as product comparison criteria. We base product comparison criteria on meaningful commercial differences among products. In other words, although there may be some physical product characteristics utilized by manufacturers to describe quartz surface products, it may be that only a select few product characteristics take into account commercially meaningful physical characteristics. In addition, interested parties may comment on the order in which the physical characteristics should be used in matching products. Generally, Commerce attempts to list the most important physical characteristics first and the least important characteristics last.

In order to consider the suggestions of interested parties in developing and issuing the AD questionnaires, all product characteristics comments must be filed by 5:00 p.m. ET on June 17, 2019, which is 20 calendar days from the signature date of this notice.[12] Any rebuttal comments must be filed by 5:00 p.m. ET on June 27, 2019. All comments and submissions to Commerce must be filed electronically using ACCESS, as explained above, on the record of each of the AD investigations.

Determination of Industry Support for the Petitions

Section 732(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 732(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (i) At least 25 percent of the total production of the domestic like product; and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition. Moreover, section 732(c)(4)(D) of the Act provides that, if the petition does not establish support of domestic producers or workers accounting for more than 50 percent of the total production of the domestic like product, Commerce shall: (i) Poll the industry or rely on other information in order to determine if there is support for the petition, as required by subparagraph (A); or (ii) determine industry support using a statistically valid sampling method to poll the ''industry.''

Section 771(4)(A) of the Act defines the ''industry'' as the producers as a whole of a domestic like product. Thus, to determine whether a petition has the requisite industry support, the statute directs Commerce to look to producers and workers who produce the domestic like product. The International Trade Commission (ITC), which is responsible for determining whether ''the domestic industry'' has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both Commerce and the ITC must apply the same statutory definition regarding the domestic like product,[13] they do so for different purposes and pursuant to a separate and distinct authority. In addition, Commerce's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to law.[14]

Section 771(10) of the Act defines the domestic like product as ''a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title.'' Thus, the reference point from which the domestic like product analysis begins is ''the article subject to an investigation'' (*i.e.,* the class or kind of merchandise to be investigated, which normally will be the scope as defined in the petitions).

With regard to the domestic like product, the petitioner does not offer a definition of the domestic like product distinct from the scope of the investigations.[15] Based on our analysis of the information submitted on the record, we have determined that quartz surface products, as defined in the scope, constitute a single domestic like product, and we have analyzed industry support in terms of that domestic like product.[16]

In determining whether the petitioner has standing under section 732(c)(4)(A) of the Act, we considered the industry support data contained in the Petitions with reference to the domestic like product as defined in the ''Scope of the Investigations,'' in the Appendix to this notice. To establish industry support, the petitioner provided its own production of the domestic like product in 2018 and compared this to the estimated total production of the domestic like product for the entire domestic industry.[17] We relied on data provided by the petitioner for purposes of measuring industry support.[18]

On May 24, 2019, we received comments on industry support from M S International, Inc. (MSI), a U.S. importer of quartz surface products from India and Turkey.[19] The petitioner responded to the industry support comments from MSI on May 28, 2019.[20] On May 28, 2019, we received comments from MSI, Bedrosians Tile & Stone, and Arizona Tile LLC, each of whom is a U.S. importer of quartz surface products from India and Turkey, pertaining to the timing of the petitioner's May 24, 2019 supplemental response.[21]

Our review of the data provided in the Petitions, the General Issues Supplement, the Third General Issues Supplement, the Petitioner's Letter, and other information readily available to Commerce indicates that the petitioner has established industry support for the Petitions.[22] With respect to the India

[12] *See* 19 CFR 351.303(b).

[13] *See* section 771(10) of the Act.

[14] *See USEC, Inc.* v. *United States,* 132 F. Supp. 2d 1, 8 (CIT 2001) (citing *Algoma Steel Corp., Ltd.* v. *United States,* 688 F. Supp. 639, 644 (CIT 1988), *aff'd* 865 F.2d 240 (Fed. Cir. 1989)).

[15] *See* Volume I of the Petitions, at 8–11 and Exhibit I–6; *see also* General Issues Supplement at 2–4.

[16] For a discussion of the domestic like product analysis as applied to this case and information regarding industry support, *see* Antidumping Duty Investigation Initiation Checklist: Certain Quartz Surface Products from India (India AD Initiation Checklist) at Attachment II; *see also* Analysis of Industry Support for the Antidumping and Countervailing Duty Petitions Covering Certain Quartz Surface Products from India and the Republic of Turkey (Attachment II); and Antidumping Duty Investigation Initiation Checklist: Certain Quartz Surface Products from the Republic of Turkey (Turkey AD Initiation Checklist), at Attachment II. These checklists are dated concurrently with this notice and on file electronically via ACCESS. Access to documents filed via ACCESS is also available in the Central Records Unit, Room B8024 of the main Department of Commerce building.

[17] *See* Volume I of the Petitions, at 2–4 and Exhibits I–3 and I–4; *see also* General Issues Supplement, at 8–9 and Exhibits 10 and 11; Third General Issues Supplement, at 3 and Exhibits 1 and 2.

[18] *See* Volume I of the Petitions, at 2–4 and Exhibits I–3 and I–4; *see also* General Issues Supplement, at 8–9 and Exhibits 10 and 11; Third General Issues Supplement, at 3 and Exhibits 1 and 2. For further discussion, *see* India AD Initiation Checklist, at Attachment II; and Turkey AD Initiation Checklist, at Attachment II.

[19] *See* MSI's letter, ''Quartz Surface Products from India and the Republic of Turkey: Comments on the Lack of Standing of the Petitioner and Requests for Action,'' dated March 20, 2019 (MSI's Letter).

[20] *See* the petitioner's letter, ''Certain Quartz Surface Products from India and the Republic of Turkey: Petitioner's Response to MSI's Comments on Standing,'' dated May 28, 2019 (Petitioner's Letter).

[21] *See* letter from MSI, Bedrosians Tile & Stone, and Arizona Tile LLC, ''Quartz Surface Products from India and the Republic of Turkey: Preliminary Comments on Petitioner's Tardy Amendment to its Petitions,'' dated May 28, 2019 (Petition Amendment Comments).

[22] *See* India AD Initiation Checklist, at Attachment II; *see also* Turkey AD Initiation Checklist, at Attachment II.

Petition, the domestic producers (or workers) have met the statutory criteria for industry support under section 732(c)(4)(A)(i) of the Act because the domestic producers (or workers) who support the India Petition account for at least 25 percent of total production of the domestic like product.[23] The India Petition also established support from domestic producers (or workers) accounting for more than 50 percent of the total production of the domestic like product and, as such, Commerce is not required to take further action in order to evaluate industry support (*e.g.,* polling).[24] Finally, the domestic producers (or workers) have met the statutory criteria for industry support under section 732(c)(4)(A)(ii) of the Act because the domestic producers (or workers) who support the India Petition account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the India Petition.[25] Accordingly, Commerce determines that the India Petition was filed on behalf of the domestic industry within the meaning of section 732(b)(1) of the Act.[26]

With respect to the Turkey Petition, the domestic producers (or workers) have met the statutory criteria for industry support under section 732(c)(4)(A)(i) of the Act because the domestic producers (or workers) who support the Turkey Petition account for at least 25 percent of total production of the domestic like product.[27] The Turkey Petition did not establish support from domestic producers (or workers) accounting for more than 50 percent of the total production of the domestic like product, however, and Commerce was required to further evaluate industry support.[28] In this case, Commerce was able to rely on other information, in accordance with section 732(c)(4)(D)(i) of the Act, to determine industry support.[29] Based on information provided in the Turkey Petition, the domestic producers (or workers) have met the statutory criteria for industry support under section 732(c)(4)(A)(ii) of the Act because the domestic producers (or workers) who support the Turkey Petition account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the Turkey Petition.[30] Accordingly, Commerce determines that the Turkey Petition was filed on behalf of the domestic industry within the meaning of section 732(b)(1) of the Act.[31]

Allegations and Evidence of Material Injury and Causation

The petitioner alleges that the U.S. industry producing the domestic like product is being materially injured, or is threatened with material injury, by reason of the imports of the subject merchandise sold at LTFV. In addition, the petitioner alleges that subject imports exceed the negligibility threshold provided for under section 771(24)(A) of the Act.[32]

The petitioner contends that the industry's injured condition is illustrated by a significant and increasing volume of subject imports; reduced market share; underselling and price depression or suppression; lost sales and revenues; and a decline in the domestic industry's employment variables and financial performance.[33] We have assessed the allegations and supporting evidence regarding material injury, threat of material injury, causation, as well as negligibility, and we have determined that these allegations are properly supported by adequate evidence, and meet the statutory requirements for initiation.[34]

Allegations of Sales at LTFV

The following is a description of the allegations of sales at LTFV upon which Commerce based its decision to initiate AD investigations of imports of quartz surface products from India and Turkey. The sources of data for the deductions and adjustments relating to U.S. price and normal value (NV) are discussed in greater detail in the country-specific AD Initiation Checklists.

Export Price

For India and Turkey, the petitioner based export price (EP) on the average unit values (AUVs) of the official U.S. import statistics obtained from the ITC's Dataweb (Dataweb). The petitioner made deductions from U.S. price for foreign inland freight and foreign brokerage and handling charges.[35]

Normal Value

For India, the petitioner based NV on a home market price quote obtained through market research for quartz surface products produced in and sold, or offered for sale, in India within the POI.[36] The petitioner provided information indicating that the price quote was below the cost of production (COP) and, therefore, the petitioner calculated NV based on CV.

For Turkey, the petitioner was unable to obtain a price quote for quartz surface products produced in and sold, or offered for sale, in Turkey that was usable for comparison to the price of quartz surface products exported to the United States from Turkey, nor was it able to obtain a suitable third country price.[37] The petitioner therefore calculated normal value based on constructed value (CV).[38]

For further discussion of CV, *see* the section ''Normal Value Based on Constructed Value'' below.[39]

Normal Value Based on Constructed Value

As noted above, the petitioner was unable to obtain information relating to the prices charged for quartz surface products produced in Turkey and sold in Turkey, or any third country market, and the price quote obtained for the sale in India was below the COP. Accordingly, the petitioner based NV on CV.[40] Pursuant to section 773(e) of the Act, CV consists of the cost of manufacturing (COM), selling, general, and administrative (SG&A) expenses, financial expenses, and profit. For India and Turkey, the petitioner calculated

[23] *See* India AD Initiation Checklist, at Attachment II.

[24] *See* section 732(c)(4)(D) of the Act; *see also* India AD Initiation Checklist, at Attachment II.

[25] *See* India AD Initiation Checklist, at Attachment II.

[26] *Id.*

[27] *See* Turkey AD Initiation Checklist, at Attachment II.

[28] *See* section 732(c)(4)(D) of the Act; *see also* Turkey AD Initiation Checklist, at Attachment II.

[29] *See* Turkey AD Initiation Checklist, at Attachment II.

[30] *Id.*

[31] *Id.*

[32] *See* Volume I of the Petitions, at 19 and Exhibit I–13; *see also* General Issues Supplement, at 10 and Exhibit 13.

[33] *See* Volume I of the Petitions, at 13, 15–40 and Exhibits I–3, I–10, I–13 through I–30; *see also* General Issues Supplement, at 10–14 and Exhibits 12 and 13.

[34] *See* India AD Initiation Checklist, at Attachment III, Analysis of Allegations and Evidence of Material Injury and Causation for the Antidumping and Countervailing Duty Petitions Covering Certain Quartz Surface Products from India and the Republic of Turkey (Attachment III); *see also* Turkey AD Initiation Checklist, at Attachment III.

[35] *See* India AD Initiation Checklist and Turkey AD Initiation Checklist.

[36] *See* India AD Initiation Checklist.

[37] *See* Turkey AD Initiation Checklist.

[38] *Id.*

[39] In accordance with section 505(a) of the Trade Preferences Extension Act of 2015, amending section 773(b)(2) of the Act, for these investigations, Commerce will request information necessary to calculate the CV and cost of production (COP) to determine whether there are reasonable grounds to believe or suspect that sales of the foreign like product have been made at prices that represent less than the COP of the product. Commerce no longer requires a COP allegation to conduct this analysis.

[40] *See* Turkey AD Initiation Checklist and India AD Initiation Checklist.

the COM based on the input factors of production and its own usage rates. The input factors of production were valued using publicly available data on costs specific to Turkey and India, during the proposed POI.[41] Specifically, the prices for raw materials and energy inputs were valued using publicly available import and domestic price data for Turkey and India.[42] Labor costs were valued using publicly available sources for Turkey and India.[43] The petitioner calculated factory overhead, SG&A expenses, financial expenses, and profit for Turkey and India based on the ratios found in the experience of a producer of identical or comparable merchandise from each of these countries.[44]

Fair Value Comparisons

Based on the data provided by the petitioner, there is reason to believe that imports of quartz surface products from India and Turkey are being, or are likely to be, sold in the United States at LTFV. Based on comparisons of EP to NV in accordance with sections 772 and 773 of the Act, the estimated dumping margin for quartz surface products from India is 323.12 percent and from Turkey is 85.71 percent.[45]

Initiation of LTFV Investigations

Based upon the examination of the AD Petitions and supplemental responses, we find that they meet the requirements of section 732 of the Act. Therefore, we are initiating AD investigations to determine whether imports of quartz surface products from India and Turkey are being, or are likely to be, sold in the United States at LTFV. In accordance with section 733(b)(1)(A) of the Act and 19 CFR 351.205(b)(1), unless postponed, we will make our preliminary determinations no later than 140 days after the date of this initiation.

Respondent Selection

In the Petitions, the petitioner named 92 companies in India[46] and 25 companies in Turkey,[47] as producers/exporters of quartz surface products. Following standard practice in AD investigations involving market economy countries, in the event Commerce determines that the number of companies is large and it cannot individually examine each company based upon Commerce's resources, where appropriate, Commerce intends to select respondents in India and Turkey based on U.S. Customs and Border Protection (CBP) data for U.S. imports under the appropriate Harmonized Tariff Schedule of the United States numbers listed in the ''Scope of the Investigations,'' in the Appendix.

On May 22, 2019, Commerce released CBP data on imports of quartz surface products from India and Turkey under APO to all parties with access to information protected by APO and indicated that interested parties wishing to comment on the CBP data must do so within three business days of the publication date of the notice of initiation of these investigations.[48] Commerce will not accept rebuttal comments regarding the CBP data or respondent selection.

Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305(b). Instructions for filing such applications may be found on the Commerce's website at *http://enforcement.trade.gov/apo*.

Comments must be filed electronically using ACCESS. An electronically filed document must be received successfully, in its entirety, by ACCESS no later than 5:00 p.m. ET on the date noted above. We intend to finalize our decisions regarding respondent selection within 20 days of publication of this notice.

Distribution of Copies of the AD Petitions

In accordance with section 732(b)(3)(A) of the Act and 19 CFR 351.202(f), copies of the public version of the AD Petitions have been provided to the governments of India and Turkey via ACCESS. To the extent practicable, we will attempt to provide a copy of the public version of the AD Petitions to each exporter named in the AD Petitions, as provided under 19 CFR 351.203(c)(2).

ITC Notification

We will notify the ITC of our initiation, as required by section 732(d) of the Act.

Preliminary Determinations by the ITC

The ITC will preliminarily determine, within 45 days after the date on which the AD Petitions were filed, whether there is a reasonable indication that imports of quartz surface products from India and/or Turkey are materially injuring, or threatening material injury to, a U.S. industry.[49] A negative ITC determination for any country will result in the investigations being terminated with respect to that country.[50] Otherwise, these AD investigations will proceed according to statutory and regulatory time limits.

Submission of Factual Information

Factual information is defined in 19 CFR 351.102(b)(21) as: (i) Evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by Commerce; and (v) evidence other than factual information described in (i)–(iv). Section 351.301(b) of Commerce's regulations requires any party, when submitting factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted[51] and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct.[52] Time limits for the submission of factual information are addressed in 19 CFR 351.301, which provides specific time limits based on the type of factual information being submitted. Interested parties should review the regulations prior to submitting factual information in these investigations.

Particular Market Situation Allegation

Section 504 of the Trade Preferences Extension Act of 2015 amended the Act by adding the concept of particular market situation (PMS) for purposes of CV under section 773(e) of the Act.[53] Section 773(e) of the Act states that ''if a particular market situation exists such that the cost of materials and fabrication or other processing of any kind does not accurately reflect the cost of production in the ordinary course of trade, the administering authority may use another calculation methodology under this subtitle or any other calculation methodology.'' When an interested party submits a PMS allegation pursuant

[41] *Id.*
[42] *Id.*
[43] *Id.*
[44] *Id.*
[45] *Id.*
[46] *See* Volume I of the Petitions, at Exhibit I–9.
[47] *Id.*
[48] *See* Memoranda, ''Antidumping Duty Investigation of Certain Quartz Surface Products from India: Release of Customs Data from U.S. Customs and Border Protection;'' and, ''Antidumping Duty Investigation of Certain Quartz Surface Products from Turkey: Release of Customs Data from U.S. Customs and Border Protection,'' dated May 22, 2019.
[49] *See* section 733(a) of the Act.
[50] *Id.*
[51] *See* 19 CFR 351.301(b).
[52] *See* 19 CFR 351.301(b)(2).
[53] *See* Trade Preferences Extension Act of 2015, Public Law 114–27, 129 Stat. 362 (2015).

to section 773(e) of the Act, Commerce will respond to such a submission consistent with 19 CFR 351.301(c)(2)(v). If Commerce finds that a PMS exists under section 773(e) of the Act, then it will modify its dumping calculations appropriately.

Neither section 773(e) of the Act nor 19 CFR 351.301(c)(2)(v) set a deadline for the submission of PMS allegations and supporting factual information. However, in order to administer section 773(e) of the Act, Commerce must receive PMS allegations and supporting factual information with enough time to consider the submission. Thus, should an interested party wish to submit a PMS allegation and supporting new factual information pursuant to section 773(e) of the Act, it must do so no later than 20 days after submission of a respondent's initial section D questionnaire response.

Extensions of Time Limits

Parties may request an extension of time limits before the expiration of a time limit established under 19 CFR 351.301, or as otherwise specified by the Secretary. In general, an extension request will be considered untimely if it is filed after the expiration of the time limit established under 19 CFR 351.301. For submissions that are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. ET on the due date. Under certain circumstances, we may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, we will inform parties in a letter or memorandum of the deadline (including a specified time) by which extension requests must be filed to be considered timely. An extension request must be made in a separate, stand-alone submission; under limited circumstances we will grant untimely-filed requests for the extension of time limits. Parties should review *Extension of Time Limits; Final Rule,* 78 FR 57790 (September 20, 2013), available at *http://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm,* prior to submitting factual information in these investigations.

Certification Requirements

Any party submitting factual information in an AD or CVD proceeding must certify to the accuracy and completeness of that information.[54] Parties must use the certification formats provided in 19 CFR 351.303(g).[55] Commerce intends to reject factual submissions if the submitting party does not comply with the applicable certification requirements.

Notification to Interested Parties

Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305. On January 22, 2008, Commerce published *Antidumping and Countervailing Duty Proceedings: Documents Submission Procedures; APO Procedures,* 73 FR 3634 (January 22, 2008). Parties wishing to participate in these investigations should ensure that they meet the requirements of these procedures (*e.g.,* the filing of letters of appearance as discussed at 19 CFR 351.103(d)).

This notice is issued and published pursuant to sections 732(c)(2) and 777(i) of the Act, and 19 CFR 351.203(c).

Dated: May 28, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix

Scope of the Investigations

The merchandise covered by the investigations is certain quartz surface products. Quartz surface products consist of slabs and other surfaces created from a mixture of materials that includes predominately silica (*e.g.,* quartz, quartz powder, cristobalite, glass powder) as well as a resin binder (*e.g.,* an unsaturated polyester). The incorporation of other materials, including, but not limited to, pigments, cement, or other additives does not remove the merchandise from the scope of the investigations. However, the scope of the investigations only includes products where the silica content is greater than any other single material, by actual weight. Quartz surface products are typically sold as rectangular slabs with a total surface area of approximately 45 to 60 square feet and a nominal thickness of one, two, or three centimeters. However, the scope of these investigations includes surface products of all other sizes, thicknesses, and shapes. In addition to slabs, the scope of these investigations includes, but is not limited to, other surfaces such as countertops, backsplashes, vanity tops, bar tops, work tops, tabletops, flooring, wall facing, shower surrounds, fire place surrounds, mantels, and tiles. Certain quartz surface products are covered by the investigations whether polished or unpolished, cut or uncut, fabricated or not fabricated, cured or uncured, edged or not edged, finished or unfinished, thermoformed or not thermoformed, packaged or unpackaged, and regardless of the type of surface finish. In addition, quartz surface products are covered by the investigations whether or not they are imported attached to, or in conjunction with, non-subject merchandise such as sinks, sink bowls, vanities, cabinets, and furniture. If quartz surface products are imported attached to, or in conjunction with, such non-subject merchandise, only the quartz surface product is covered by the scope.

Subject merchandise includes material matching the above description that has been finished, packaged, or otherwise fabricated in a third country, including by cutting, polishing, curing, edging, thermoforming, attaching to, or packaging with another product, or any other finishing, packaging, or fabrication that would not otherwise remove the merchandise from the scope of the investigations if performed in the country of manufacture of the quartz surface products. The scope of the investigations does not cover quarried stone surface products, such as granite, marble, soapstone, or quartzite. Specifically excluded from the scope of the investigations are crushed glass surface products. Crushed glass surface products must meet each of the following criteria to qualify for this exclusion: (1) The crushed glass content is greater than any other single material, by actual weight; (2) there are pieces of crushed glass visible across the surface of the product; (3) at least some of the individual pieces of crushed glass that are visible across the surface are larger than 1 centimeter wide as measured at their widest cross-section (Glass Pieces); and (4) the distance between any single Glass Piece and the closest separate Glass Piece does not exceed three inches.

The products subject to the scope are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under the following subheading: 6810.99.0010. Subject merchandise may also enter under subheadings 6810.11.0010, 6810.11.0070, 6810.19.1200, 6810.19.1400, 6810.19.5000, 6810.91.0000, 6810.99.0080, 6815.99.4070, 2506.10.0010, 2506.10.0050, 2506.20.0010, 2506.20.0080, and 7016.90.1050. The HTSUS subheadings set forth above are provided for convenience and U.S. Customs purposes only. The written description of the scope is dispositive.

[FR Doc. 2019–11488 Filed 5–31–19; 8:45 am]

BILLING CODE 3510–DS–P

[54] *See* section 782(b) of the Act.

[55] *See 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.*

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Institute of Standards and Technology (NIST).

Title: NIST Generic Clearance for Program Evaluation Data Collections.

OMB Control Number: #0693–0033.

Form Number(s): None.

Type of Request: Regular submission (revision and extension of a currently approved information collection.)

Number of Respondents: 40,000.

Average Hours Per Response: Varied dependent upon the individual data collection. Response time could be 2 minutes for a response card or 1 hour for a more structured collection instrument. The overall average response time is expected to be 30 minutes.

Burden Hours: 20,000.

Needs and Uses: In accordance with Executive Order 12862, the National Institute of Standards and Technology (NIST), a non-regulatory agency of the Department of Commerce (DoC), proposes to conduct a number of surveys both quantitative and qualitative-designed to evaluate our current program evaluation data collections by means of, but not limited to, focus groups, reply cards that accompany product distributions, and Web-based surveys and dialogue boxes that offer customers an opportunity to express their views on the programs they are asked to evaluate. NIST will limit its inquires to data collections that solicit strictly voluntary opinions and will not collect information that is required or regulated. Steps will be taken to assure anonymity covered under this request.

Affected Public: Business or other for profit organizations, not-for-profit institutions, individuals or households, Federal government, State, Local or Tribal Government.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

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

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

Sheleen Dumas,

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

[FR Doc. 2019–11454 Filed 5–31–19; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XH052

Western Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting and hearing.

SUMMARY: The Western Pacific Fishery Management Council (Council) will hold a meeting of its Hawaii Archipelago Fishery Ecosystem Plan (FEP) Advisory Panel (AP) to discuss and make recommendations on fishery management issues in the Western Pacific Region.

DATES: The Hawaii Archipelago FEP AP will meet on Thursday, June 20, 2019, between 9 a.m. and 12 noon. All times listed are local island times. For specific times and agendas, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The Hawaii Archipelago FEP AP will meet at the Council Office, 1164 Bishop St., Suite 1400, Honolulu, HI 96813.

FOR FURTHER INFORMATION CONTACT: Kitty M. Simonds, Executive Director, Western Pacific Fishery Management Council; telephone: (808) 522–8220.

SUPPLEMENTARY INFORMATION: Public comment periods will be provided in the agenda. The order in which agenda items are addressed may change. The meetings will run as late as necessary to complete scheduled business.

Schedule and Agenda for the Hawaii Archipelago FEP AP Meeting

Thursday, June 20, 2019, 9 a.m.–12 Noon

1. Welcome and Introductions
2. Review of the last AP meeting and recommendations
3. Council Issues
A. Kona Crab Fishery Annual Catch Limits
B. Annual SAFE Report Updates
4. Hawaii Reports
A. Community Report
B. Education Report
C. Island Report
D. Legislative Report
5. Report on Hawaii Archipelago FEP Advisory Panel Plan
6. Hawaii AP Fishery Issues and Activities
7. Public Comment
8. Discussion and Recommendations
9. Other Business

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kitty M. Simonds, (808) 522–8220 (voice) or (808) 522–8226 (fax), at least 5 days prior to the meeting date.

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

Dated: May 28, 2019.

Rey Israel Marquez,

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

[FR Doc. 2019–11441 Filed 5–31–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG989

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic, Shrimp Fishery of the Gulf of Mexico; Exempted Fishing Permits

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

ACTION: Notice of receipt of an application for exempted fishing permit; request for comments.

SUMMARY: NMFS announces the receipt of an application for an exempted fishing permit (EFP) from Dr. Glenn Parsons, University of Mississippi. If granted, the EFP would authorize the use of an experimental bycatch reduction device (BRD) in the shrimp trawl fishery in Federal waters of the Gulf of Mexico (Gulf). The project would seek feedback on industry acceptance of the experimental BRD and provide informal comparisons between the experimental BRD and currently certified BRDs during normal shrimp trawl fishing operations.

DATES: Written comments must be received on or before June 18, 2019.

ADDRESSES: You may submit comments on the application, identified by ''NOAA–NMFS–2019–0052'' by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2019-0052,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Frank Helies, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701.

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

Electronic copies of the application may be obtained from the Southeast Regional Office website at *https://www.fisheries.noaa.gov/southeast/commercial-fishing/experimental-shrimp-trawl-bycatch-reduction-device*.

FOR FURTHER INFORMATION CONTACT: Frank Helies, 727–824–5305; email: *frank.helies@noaa.gov*.

SUPPLEMENTARY INFORMATION: The EFP is requested under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*), and regulations at 50 CFR 600.745(b) concerning exempted fishing.

The EFP application submitted to NMFS involves the use of experimental gear in Federal waters. Federal regulations require most shrimp vessels to use NMFS approved bycatch reduction devices (BRD) while shrimp trawling in Federal waters in the Gulf (50 CFR 622.53). The EFP would exempt seven vessels from the BRD requirement to allow the applicant to replace an existing approved BRD with the experimental BRD.

The primary goal of the project is to solicit industry feedback on the Nested Cylinder BRD (NCBRD) to determine whether to seek certification by NMFS and market this new type of BRD to the shrimp industry. The NCBRD has been in development since 2015, with the research work funded through NMFS grant programs. The NCBRD exploits the natural tendency for fish to swim up current and to take refuge in reduced flow areas created by the device. The NCBRD is sewn into the trawl ''bag'' downstream of the turtle excluder device (TED). The NCBRD is constructed with a continuous flow-blocking collar made of galvanized steel or marine grade aluminum, which creates a region of reduced flow that attracts fish. This reduced flow area is adjacent to large mesh netting (11.5 cm square) that encircles the NCBRD to create escape openings and provides the opportunity for fish to exit the trawl. The webbing extension on the front of the NCBRD measures 120 meshes in circumference, four meshes in length, where the mesh in place is 41 mm stretch mesh. A 40-inch (104-cm) long webbing ''funnel'' connects to the inner cylinder of the NCBRD and is 60 meshes in circumference, 26 meshes in length, and uses 41 mm stretch mesh. The funnel displaces all organisms downstream of the escape opening such that the fish must swim upstream into the flow ''shadow'' to exit the trawl. Two floats attached to the top of the device provide flotation to prevent scuffing of the gear on the ocean bottom.

Since 2015, the NCBRD has been used on a variety of Gulf and South Atlantic commercial shrimp vessels contracted for research evaluation in Federal waters. Successful NMFS at-sea NCBRD certification trials were completed in December 2016, as prescribed in the BRD Testing Protocol Manual (81 FR 95056, December 27, 2016). Under this EFP, an existing certified BRD on seven Gulf shrimp vessels would be replaced with the NCBRD in one outboard net during normal fishing operations. This will allow for comparison between the different BRDs. The applicant intends to obtain opinions, comments, and suggestions from Gulf shrimpers that might encourage them to use the device. To ensure proper use of the NCBRD, the applicant would make site visits to each participant to demonstrate proper installation in the trawl and request shrimpers use the device for at least 30 trawls during normal fishing operations. All trawling would be conducted in the northern Gulf shrimp grounds offshore of Alabama, Louisiana, Mississippi, and Texas. Depths typically range from a few meters out to approximately 65 meters. Tow times would be no less than 1 hour in duration. All shrimp trawlers would still be required to comply with the TED regulations at 50 CFR 223.206(d)(2).

The applicant has requested the EFP be effective for one year from the date of issuance.

NMFS finds the application warrants further consideration based on a preliminary review. Possible conditions the agency may impose on the permit, if granted, include but are not limited to, a prohibition on conducting activities within marine protected areas, marine sanctuaries, special management zones, or areas where they might interfere with managed fisheries without additional authorization. A final decision on issuance of the EFP will depend on NMFS' review of public comments received on the application, consultations with the appropriate fishery management agencies of the affected states, Councils, and the U.S. Coast Guard, and a determination that the activities to be taken under the EFP are consistent with all applicable laws and regulations.

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

Dated: May 28, 2019.

Jennifer M. Wallace,

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

[FR Doc. 2019–11455 Filed 5–31–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XH053

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council (Council) will hold a meeting to get public feedback on the Saltonstall-Kennedy Grant Program.

DATES: The meeting will be held on Friday, June 14, 2019 at 10:30 a.m. For agenda details, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The meeting will be held via webinar, and a link will be posted to the Council's website: *www.mafmc.org*.

Council address: Mid-Atlantic Fishery Management Council, 800 N. State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331 or on their website at *www.mafmc.org*.

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to obtain public feedback and recommendations from fishing community constituents on ways to improve communications, dissemination, and utilization of results achieved through projects funded by the Saltonstall-Kennedy (S–K) Grant Program. Each year, S–K awards approximately $10 million to fisheries research and development projects (up to $300,000 per project). These projects are selected based on criteria used to determine how well they address the needs of fishing communities,

demonstrate direct benefits to U.S. fishing industries (including both commercial and recreational fisheries), and involve fishing community participation.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to M. Jan Saunders, (302) 526–5251, at least 5 days prior to any meeting date.

Dated: May 28, 2019.

Rey Israel Marquez,

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

[FR Doc. 2019–11440 Filed 5–31–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XH051

Fisheries of the Gulf of Mexico; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

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

ACTION: Notice of SEDAR 62 Assessment Webinar I for Gulf of Mexico gray triggerfish.

SUMMARY: The SEDAR 62 stock assessment process for Gulf of Mexico gray triggerfish will consist of an In-person Workshop, and a series of data and assessment webinars. See **SUPPLEMENTARY INFORMATION.**

DATES: The SEDAR 62 Assessment Webinar I will be held June 20, 2019, from 10 a.m. until 12 p.m. Eastern Time.

ADDRESSES: The meeting will be held via webinar. The webinar is open to members of the public. Those interested in participating should contact Julie A. Neer at SEDAR (see **FOR FURTHER INFORMATION CONTACT**) to request an invitation providing webinar access information. Please request webinar invitations at least 24 hours in advance of each webinar.

SEDAR address: 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Julie A. Neer, SEDAR Coordinator; (843) 571–4366; email: *Julie.neer@safmc.net.*

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a multi-step process including: (1) Data Workshop, (2) a series of assessment webinars, and (3) A Review Workshop. The product of the Data Workshop is a report that compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The assessment webinars produce a report that describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The product of the Review Workshop is an Assessment Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, HMS Management Division, and Southeast Fisheries Science Center. Participants include data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and NGO's; International experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion during the Assessment Webinar are as follows:

1. Using datasets and initial assessment analysis recommended from the in-person workshop, panelists will employ assessment models to evaluate stock status, estimate population benchmarks and management criteria, and project future conditions.
2. Participants will recommend the most appropriate methods and configurations for determining stock status and estimating population parameters.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see **ADDRESSES**) at least 5 business days prior to each workshop.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: May 28, 2019.

Rey Israel Marquez,

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

[FR Doc. 2019–11442 Filed 5–31–19; 8:45 am]

BILLING CODE 3510–22–P

COMMISSION OF FINE ARTS

Notice of Meeting

The next meeting of the U.S. Commission of Fine Arts is scheduled for 20 June 2019, at 9:00 a.m. in the Commission offices at the National Building Museum, Suite 312, Judiciary Square, 401 F Street NW, Washington, DC 20001–2728. Items of discussion may include buildings, parks and memorials.

Draft agendas and additional information regarding the Commission are available on our website: *www.cfa.gov.* Inquiries regarding the agenda and requests to submit written or oral statements should be addressed to Thomas Luebke, Secretary, U.S. Commission of Fine Arts, at the above address; by emailing *cfastaff@cfa.gov;* or by calling 202–504–2200. Individuals requiring sign language interpretation for the hearing impaired should contact the Secretary at least 10 days before the meeting date.

Dated May 17, 2019 in Washington DC.

Thomas Luebke,

Secretary.

[FR Doc. 2019–11078 Filed 5–31–19; 8:45 am]

BILLING CODE M

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2019–OS–0064]

Privacy Act of 1974; System of Records

AGENCY: Defense Logistics Agency, DoD.

ACTION: Notice of a modified system of records.

SUMMARY: The Defense Logistics Agency (DLA) is proposing to modify the system

of records notice, ''Defense Agencies Initiative (DAI) Civilian Time and Labor Records,'' S890.11. The DAI is the target financial management system for the Department of Defense (DoD) and is required to eliminate or replace DoD financial management systems that are duplicative, redundant, or fail to comply with the standards set forth in the Federal Financial Management Improvement Act, and other relevant Federal and DoD policies. The modifications to this System of Records Notice (SORN) are necessary since the DAI system has undergone several enhancements necessitating changes to several sections of the SORN and to ensure the SORN meets OMB Circular A–108 requirements. As a result, this SORN proposes changes to the system name, system location, system manager(s) and address, authorities, purpose, categories of individuals, categories of records, record source categtories, routine uses, storage of records, retrieval of records, retention and disposal of records, record access procedures, and notification procedures.

DATES: Comments will be accepted on or before July 3, 2019. This proposed action will be effective the date following the end of the comment period unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

* *Federal eRulemaking Portal: http://www.regulations.gov.*

Follow the instructions for submitting comments.

* *Mail:* Department of Defense, Office of the Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Lewis W. Oleinick, Chief Privacy Officer, Defense Logistics Agency, ATTN: J–67C, Room 1567, 8725 John J. Kingman Road, Fort Belvoir, VA 22060, or by phone at (571) 767–6194.

SUPPLEMENTARY INFORMATION: The DAI system transforms the budget, finance, and accounting operations of the defense agencies in order to obtain accurate and reliable financial information necessary to support financial accountability and promote effective and efficient management decision making. The National Defense Authorization Act for Fiscal Year 2008, Public Law 110–181, Sec. 1005, required, in relevant part, the DAI program to include: Procure to Pay, including payments for tuition reimbursement when an employee pays out of pocket for a class; Order to Fulfill, including tracking overpayment to an employee from the Defense Travel System; and, Time and Attendance and Employee Entitlement. Employee Entitlement includes such items as payroll, awards, bonuses, permanent change of station (PCS), temporary duty (TDY), and miscellaneous reimbursements.

The DLA SORNs subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in the **FOR FURTHER INFORMATION CONTACT** section or from the Defense Privacy, Civil Liberties, and Transparency Division website: *http://dpcld.defense.gov.*

The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on April 10, 2019, to the House Committee on Oversight and Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to Section 6 of OMB Circular No. A–108, ''Federal Agency Responsibilities for Review, Reporting, and Publication under the Privacy Act,'' revised December 23, 2016 (December 23, 2016, 81 FR 94424).

Dated: May 29, 2019.

Aaron T. Siegel,

Alternate OSD **Federal Register** *Liaison Officer, Department of Defense.*

SYSTEM NAME AND NUMBER

Defense Agencies Initiative (DAI), S890.11.

SECURITY CLASSIFICATION

Unclassified.

SYSTEM LOCATION:

Defense Logistics Agency (DLA), 8725 John J. Kingman Rd., Fort Belvoir, VA 22060–6221.

Defense Information Systems Agency, Defense Enterprise Computing Center Ogden, 7879 Wardleigh Road, Hill AFB, UT 84056–5997.

SYSTEM MANAGER(S):

Program Manager, Defense Agencies Initiative (DAI) Program Management Office, 5611 Columbia Pike, 3rd Floor, Falls Church, VA 22041–6221, or by email at *DAI@dla.mil.*

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. Chapter 61, Hours of Work; 5 U.S.C. Chapter 53, Pay Rates and Systems; 5 U.S.C. Chapter 57, Travel, Transportation, and Subsistence; 5 U.S.C. Chapter 63, Leave; 10 U.S.C. 136, Under Secretary of Defense for Personnel and Readiness; 31 U.S.C. Chapter 35, Accounting and Collection; 10 U.S.C. 2222 note, Financial Management Transformation Initiative for the Defense Agencies; 31 U.S.C. 3512, Executive Agency Accounting and Other Financial Management Reports and Plans, as amended; The National Defense Authorization Act for Fiscal Year 2008, Public Law 110–181, Sec. 1005; and E.O. 9397 (SSN), as amended.

PURPOSE(S) OF THE SYSTEM:

Records are used to make payments for tuition reimbursement when an employee pays out of pocket for a class; to track overpayment to an employee from the Defense Travel System; to track payroll, awards, bonuses, permanent change of station (PCS) payments, temporary duty (TDY) payments, and miscellaneous payment reimbursements; to prepare time and attendance records; to record employee pay rates and status, including overtime, the use of leave, and work absences; to track workload, project activity for analysis and reporting purposes; for statistical reporting on leave and overtime use/usage patterns, and to answer employee queries on leave, overtime, and pay.

Information from this system of records is provided to the Defense Civilian Payroll System (DCPS) for issuing payroll.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

DoD civilian employees receiving accounting and financial management support from DAI under Memoranda of Agreement or Memoranda of Understanding.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records maintained include individual's name, Social Security Number (SSN), DoD Identification Number (DoD ID), mailing address, citizenship, pay, gender, employee's status, position, accounting codes, organization and office location, email address, pay rate, leave balances; work and shift schedule, project and

workload records, regular and overtime work hours, leave hours, time and attendance records (timesheet), and information on telework, temporary duty and special assignments; permanent change of station (PCS), temporary duty (TDY), and travel voucher information such as travel authorization number, moving costs, apartment rent, hotels, rental car fees, and airfare; for miscellaneous pay, categories of payment and amount; for over or under payment, payment amount made by DFAS; for tuition reimbursement, educational institution, name of course, cost of tuition and fees, dates of attendance.

RECORD SOURCE CATEGORIES:

The individual, supervisors, timekeepers, leave slips and automated payroll systems, such as, the Defense Civilian Payroll System, and the Defense Travel System.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act of 1974, as amended, records contained herein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

a. To the Office of Personnel Management (OPM) for the purpose of addressing civilian pay and leave, benefits, retirement deduction, and any other information necessary for the OPM to carry out its legally authorized Government-wide personnel management functions and studies.

b. To contractors performing or working on a contract for the Federal Government when necessary to accomplish an agency function related to this system of records.

c. To unions recognized as exclusive bargaining representatives under the Civil Service Reform Act of 1978, 5 U.S.C. 7111 and 7114, the Merit Systems Protection Board, arbitrators, the Federal Labor Relations Authority, and other parties responsible for the administration of the Federal labor-management program for the purpose of processing any corrective actions, or grievances, or conducting administrative hearings or appeals.

d. To the Merit Systems Protection Board and the Office of the Special Counsel for the purpose of litigation, including administrative proceedings, appeals, special studies of the civil service and other merit systems; review of OPM or component rules and regulations; investigation of alleged or possible prohibited personnel practices, including administrative proceedings involving any individual subject of a DoD investigation.

e. To the appropriate Federal, state, local, territorial, tribal, foreign, or international law enforcement authority or other appropriate entity where a record, either alone or in conjunction with other information, indicates a violation or potential violation of law, whether criminal, civil, or regulatory in nature.

f. To any component of the Department of Justice for the purpose of representing the DoD, or its components, officers, employees, or members in pending or potential litigation to which the record is pertinent.

g. In an appropriate proceeding before a court, grand jury, or administrative or adjudicative body or official, when the DoD or other agency representing the DoD determines the records are relevant and necessary to the proceeding; or in an appropriate proceeding before an administrative or adjudicative body when the adjudicator determines the records to be relevant to the proceeding.

h. To the National Archives and Records Administration for the purpose of records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906.

i. To a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record.

j. To appropriate agencies, entities, and persons when (1) the DoD suspects or confirms a breach of the system of records; (2) the DoD determines as a result of the suspected or confirmed breach there is a risk of harm to individuals, the DoD (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the DoD's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

k. To another Federal agency or Federal entity when the DoD determines information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Electronic storage media.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are primarily retrieved by employee's name, SSN or DoD ID number.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Data from Leave Application Files (signed OPM–71 [or equivalent] and online leave requests) are destroyed after Government Accountability Office (GAO) audit or when 3 years old, whichever is sooner.

Time and Labor Source Records and Input Records are destroyed after GAO audit or when 6 years old, whichever is sooner.

Leave records are destroyed when 3 years old. Payroll system reports and data used for personnel management purposes are destroyed when 2 years old.

Project and Workload Records are destroyed after 6 years, 3 months, or when no longer needed. Travel (including TDY and PCS), Tuition Reimbursement, and Miscellaneous Payment. Transaction Data, Financial, and Accounting Records are destroyed after 6 years, 3 months, or when no longer needed for audit purposes.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Records are maintained in a controlled facility. Physical entry is restricted by the use of locks, guards, and is accessible only to authorized personnel. Access to computerized data is restricted by Common Access Cards. Access to records is limited to person(s) responsible for servicing the records in the performance of their official duties and who are properly screened and cleared for need-to-know. All individuals granted access to this system of records are required to have taken Information Assurance and Privacy Act training.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system of records should address written requests to the DLA FOIA/Privacy Act Office, Headquarters, Defense Logistics Agency, ATTN: J67CC, 8725 John J. Kingman Road, Room 1567, Fort Belvoir, VA 22060–6221. Signed, written requests should contain the full name, identifier (*i.e.,* SSN or DoD ID), current address and

telephone number of the individual. In addition, the requester must provide either a notarized statement or a declaration made in accordance with 28 U.S.C. 1746, using the following format: If executed outside the United States: ''I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date). (Signature).

If executed within the United States, its territories, possessions, or commonwealths: ''I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date). (Signature).

CONTESTING RECORD PROCEDURES:

The DoD rules for accessing records, contesting contents, and appealing initial agency determinations are contained in 32 CFR part 310, or may be obtained from the DLA FOIA/Privacy Act Office, Headquarters, Defense Logistics Agency, ATTN: J67CC, 8725 John J. Kingman Road, Room 1567, Fort Belvoir, VA 22060–6221.

NOTIFICATION PROCEDURES:

Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to the DLA FOIA/Privacy Act Office, Headquarters, Defense Logistics Agency, ATTN: J67CC, 8725 John J. Kingman Road, Rm. 1567, Fort Belvoir, VA 22060–6221.

The inquiry should contain the record subject's full name, DoD ID Number and return mailing address. Signed, written requests should contain the individual's full name, identifier (*i.e.,* SSN or DoD ID), current address and telephone number of the individual.

In addition, the requester must provide either a notarized statement or an unsworn declaration made in accordance with 28 U.S.C. 1746 in the following format:

If executed outside the United States: ''I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date). (Signature).

If executed within the United States, its territories, possessions, or commonwealths: ''I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature).

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

November 4, 2013, 78 FR 65976.

[FR Doc. 2019–11470 Filed 5–31–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2019–ICCD–0041]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; 2016/20 Baccalaureate and Beyond (B&B:16/20) Full-Scale Study Panel Maintenance

AGENCY: National Center for Education Statistics (NCES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before July 3, 2019.

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–2019–ICCD–0041. 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. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov*. Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *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 9089, Washington, DC 20202–0023.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Kashka Kubzdela, 202–245–7377 or email *NCES.Information.Collections@ed.gov*.

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: 2016/20 Baccalaureate and Beyond (B&B:16/20) Full-Scale Study Panel Maintenance.

OMB Control Number: 1850–0926.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 3,790.

Total Estimated Number of Annual Burden Hours: 190.

Abstract: This request is for the National Center for Education Statistics (NCES) to conduct the 2016/20 Baccalaureate and Beyond (B&B:16/20) full-scale study panel maintenance activities. The B&B studies of the education, work, financial, and personal experiences of individuals who have completed a bachelor's degree at a given point in time are a series of longitudinal studies. Every 8 years, students are identified as bachelor's degree recipients through the National Postsecondary Student Aid Study (NPSAS). B&B:16/20 is the second follow-up of a panel of baccalaureate degree recipients identified in the 2015–16 NPSAS, and part of the fourth cohort (B&B:16) of the B&B series. NPSA:16 is the base year for B&B:16 follow-up interviews in 2017, 2020, and 2026 (anticipated). B&B cohorts prior to B&B:16 were approved under OMB #1850–0729. The B&B:16 cohort is

submitted and reviewed under OMB #1850–0926. The primary purposes of the B&B studies are to describe the post-baccalaureate paths of new college graduates, with a focus on their experiences in the labor market and post-baccalaureate education, and their education-related debt. B&B also focuses on the continuing education paths of science, technology, engineering, and mathematics (STEM) graduates, as well as the experiences of those who have begun careers in education of students through the 12th grade. Since graduating from college in 2014–15 for the field test, and 2015–16 for the full-scale study, members of this B&B:16 cohort will begin moving into and out of the workforce, enrolling in additional undergraduate and graduate education, forming families, and repaying undergraduate education-related debt. Documenting these choices and pathways, along with individual, institutional, and employment characteristics that may be related to those choices, provides critical information on the costs and benefits of a bachelor's degree in today's workforce. B&B studies include both traditional-age and non-traditional-age college graduates, whose education options and choices often diverge considerably, and allow study of the paths taken by these different graduates. B&B:16/20 full-scale study student interview data collection is scheduled to take place from July 2020 through March 2021, and the panel maintenance activity requested in this submission is scheduled to take place from October 2019 through February 2020.

Dated: May 29, 2019.

Kate Mullan,

PRA Coordinator, Information Collection Clearance Program, Information Management Branch, Office of the Chief Information Officer.

[FR Doc. 2019–11451 Filed 5–31–19; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2019–ICCD–0069]

Agency Information Collection Activities; Comment Request; Federal Perkins Loan Program Regulations

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 August 2, 2019.

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–2019–ICCD–0069. 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. If the regulations.gov site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov*. Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *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: Federal Perkins Loan Program Regulations.

OMB Control Number: 1845–0023.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: Individuals or Households; State, Local, and Tribal Governments; Private Sector.

Total Estimated Number of Annual Responses: 8,217,172.

Total Estimated Number of Annual Burden Hours: 149,369.

Abstract: Institutions of higher education made Federal Perkins loans. This information is necessary to monitor a school's due diligence in its contact with the borrower regarding repayment, billing and collections, reimbursement to its Perkins loan revolving fund, rehabilitation of defaulted loans as well as institutions use of third party collections. There has been no change to the regulations this is a request for an extension of the currently approved reporting and record-keeping requirements contained in the regulations related to the administrative requirements of the Perkins Loan Program.

Dated: May 29, 2019.

Kate Mullan,

PRA Coordinator, Information Collection Clearance Program, Information Management Branch, Office of the Chief Information Officer.

[FR Doc. 2019–11495 Filed 5–31–19; 8:45 am]

BILLING CODE 4000–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2013–0337; FRL—9993–67–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Portland Cement Manufacturing Industry (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), NESHAP for Portland Cement Manufacturing Industry (EPA ICR Number 1801.13, OMB Control Number 2060–0416), to the Office of Management and Budget (OMB) for review and approval in accordance with

the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through May 31, 2019. Public comments were previously requested, via the **Federal Register**, on May 30, 2018 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before July 3, 2019.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2013–0337, to: (1) EPA online using *www.regulations.gov* (our preferred method), or by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460; and (2) OMB via email to *oira_submission@omb.eop.gov*. Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change, including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–2970; fax number: (202) 564–0050; email address: *yellin.patrick@epa.gov*.

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit: *http://www.epa.gov/dockets*.

Abstract: The National Emission Standards for Hazardous Air Pollutants (NESHAP) for Portland Cement Manufacturing Industry (40 CFR part 63, subpart LLL) apply to affected facilities at each new and existing portland cement manufacturing plant that is either a major or area source, including each: Kiln including alkali bypasses and inline coal mills; clinker cooler; raw mill; finish mill; raw material dryer; or open clinker storage pile. These regulations apply to each new and existing categories: Raw material, clinker or finished product storage bin; conveying system transfer point including those associated with coal preparation used to convey coal from the mill to the kiln; and bagging and bulk loading and unloading system piles located at any portland cement manufacturing plant that is a major source. These regulations do not apply to cement kilns that burn hazardous waste and are subject to 40 CFR part 63, subpart EEE, or to cement kilns that burn nonhazardous solid waste and are subject to the requirements of 40 CFR part 60, subpart CCCC, or 40 CFR part 60, subpart DDDD. This information is being collected to assure compliance with 40 CFR part 63, subpart LLL.

In general, all NESHAP standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. They are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance, and are required of all affected facilities subject to NESHAP.

Form Numbers: None.

Respondents/affected entities: These regulations apply to affected facilities at each new and existing portland cement manufacturing plant that is a major or area source, including each: Kiln including alkali bypasses and inline coal mills; clinker cooler; raw mill; finish mill; raw material dryer; or open clinker storage pile. These regulations apply to each new and existing: Raw material, clinker or finished product storage bin; conveying system transfer point including those associated with coal preparation used to convey coal from the mill to the kiln; and bagging and bulk loading and unloading system piles located at any portland cement manufacturing plant that is a major source. These regulations do not apply to cement kilns that burn hazardous waste and are subject to 40 CFR part 63, subpart EEE, or to cement kilns that burn nonhazardous solid waste and are subject to the requirements of 40 CFR part 60, subpart CCCC, or 40 CFR part 60, subpart DDDD. This information is being collected to assure compliance with 40 CFR part 63, subpart LLL.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart LLL).

Estimated number of respondents: 40 (total).

Frequency of response: Semiannually and annually.

Total estimated burden: 12,200 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $6,100,000 (per year), which includes $4,730,000 in annualized capital/startup and/or operation & maintenance costs.

Changes in the Estimates: There is an adjustment decrease in the total estimated burden as currently identified in the OMB Inventory of Approved Burdens. The adjustment decrease in burden from the most recently-approved ICR is due to a decrease in the number of sources subject to requirement of 40 CFR part 63, subpart LLL. The EPA determined that many of the cement kilns previously thought subject to 40 CFR part 63, subpart LLL are already subject to 40 CFR part 63, subpart EEE, 40 CFR part 60, subpart CCCC, or 40 CFR part 60, subpart DDDD, and would not fall under the applicability of this subpart. The decrease in the number of respondents also results in a decrease in the number of responses and operation and maintenance costs. Additionally, Table 1 was revised and reformatted to properly reflect the performance testing requirements for new and existing facilities as stated in subpart LLL.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2019–11568 Filed 5–30–19; 4:15 pm]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2012–0527; FRL–9994–31–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Paints and Allied Products Manufacturing Area Source Category (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), NESHAP for Paints and Allied Products Manufacturing Area Source Category (EPA ICR Number 2348.05, OMB

Control Number 2060–0633), to the Office of Management and Budget (OMB), for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through May 31, 2019. Public comments were previously requested, via the **Federal Register**, on May 30, 2018 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before July 3, 2019.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2012–0527 to: (1) EPA online using *www.regulations.gov* (our preferred method), or by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460; and (2) OMB via email to *oira_submission@omb.eop.gov*. Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change, including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–2970; fax number: (202) 564–0050; email address: *yellin.patrick@epa.gov*.

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit: *http://www.epa.gov/dockets*.

Abstract: The National Emission Standards for Hazardous Air Pollutants (NESHAP) for Paints and Allied Products Manufacturing Area Source Category (40 CFR part 63) were proposed on June 1, 2009, and promulgated on December 3, 2009. These regulations apply to existing facilities and new facilities that are an area source of hazardous air pollutants (HAP) emissions and that either use or have the potential to emit urban air toxics (*i.e.,* benzene; methylene chloride; cadmium, chromium, lead, and nickel compounds). New facilities include those that commenced construction or reconstruction after the date of proposal. This information is being collected to assure compliance with 40 CFR part 63, subpart CCCCCCC.

In general, all NESHAP standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. They are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance, and are required of all affected facilities subject to NESHAP.

Form Numbers: None.

Respondents/affected entities: Paints and allied products manufacturing facilities.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart CCCCCCC)

Estimated number of respondents: 219 (total).

Frequency of response: Initially and semiannually.

Total estimated burden: 500 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $131,000 (per year), which includes $0 in annualized capital/startup and/or operation & maintenance costs.

Changes in the Estimates: There is an adjustment decrease in the total estimated burden as currently identified in the OMB Inventory of Approved Burdens; this decrease is not due to any program changes. The decrease in burden is due to more accurate estimates of existing sources based on information gathered by industry. Specifically, the American Coatings Association (ACA) provided that the previous estimate of 2,190 sources is based on the 2009 proposed rule, which relied on 2002 U.S. Census data to identify 2,510 paints and allied products manufacturing facilities, of which 2,190 were further estimated to be small business and assumed to be area sources of HAP. However, the final rule made clarifications on the applicability of the NESHAP, including that final rule did not include retail and commercial paints and allied products operations which add and mix pigments to pre-manufactured products per customer specifications; that the rule does not apply to activities conducted by end users of coating products in preparation for application; and that the Generally Available Control Technology (GACT) requirements only apply when the target HAP are being processed, used, or generated (rather than at all times regardless of whether any of the target HAP was or was not being used). The ACA indicated that because the final rule only applies to those facilities that use the HAPs of concern (benzene, methylene chloride, or compounds of cadmium, chromium, lead, and/or nickel, in amounts greater than or equal to 0.1 percent by weight), the number of affected facilities is much smaller than what was initially proposed. The ACA stated that only 10% of paint and allied products facilities (or 219 of the 2,190 small sources identified in the 2009 final rule and prior ICR) would use the HAPs of concern (benzene, methylene chloride, or compounds of cadmium, chromium, lead, and/or nickel, in amounts greater than or equal to 0.1 percent by weight). Therefore, this ICR adjusts the total number of respondents to 219. The decrease in the number of respondents also results in a decrease in responses.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2019–11275 Filed 5–31–19; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

[BAC 6735–01]

Sunshine Act Meetings

May 30, 2019.

TIME AND DATE: 10:00 a.m., Thursday, June 13, 2019.

PLACE: The Richard V. Backley Hearing Room, Room 511N, 1331 Pennsylvania Avenue NW, Washington, DC 20004 (enter from F Street entrance).

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will consider and act upon the following in open session: *Secretary of Labor* v. *Solar Sources Mining, LLC,* Docket No. LAKE 2017–99. (Issues include whether the Judge abused his discretion and failed to adequately explain the basis for the civil penalty he imposed.)

Any person attending this meeting who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission in advance of those needs. Subject to 29 CFR 2706.150(a)(3) and 2706.160(d).

CONTACT PERSON FOR MORE INFO: Emogene Johnson (202) 434–9935/(202) 708–9300 for TDD Relay/1–800–877–8339 for toll free.

PHONE NUMBER FOR LISTENING TO MEETING: 1–(866) 867–4769, Passcode: 678–100.

Sarah L. Stewart,

Deputy General Counsel.

[FR Doc. 2019–11635 Filed 5–30–19; 4:15 pm]

BILLING CODE 6735–01–P

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

Sunshine Act Meetings

May 30, 2019.

TIME AND DATE: 10:00 a.m., Wednesday, June 12, 2019.

PLACE: The Richard V. Backley Hearing Room, Room 511N, 1331 Pennsylvania Avenue NW, Washington, DC 20004 (enter from F Street entrance).

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will hear oral argument in the matter *Secretary of Labor* v. *Solar Sources Mining, LLC,* Docket No. LAKE 2017–99. (Issues include whether the Judge abused his discretion and failed to adequately explain the basis for the civil penalty he imposed.)

Any person attending this oral argument who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission in advance of those needs. Subject to 29 CFR 2706.150(a)(3) and § 2706.160(d).

CONTACT PERSON FOR MORE INFO: Emogene Johnson (202) 434–9935/(202) 708–9300 for TDD Relay/1–800–877–8339 for toll free.

PHONE NUMBER FOR LISTENING TO MEETING: 1–(866) 867–4769, Passcode: 678–100.

Sarah L. Stewart,

Deputy General Counsel.

[FR Doc. 2019–11633 Filed 5–30–19; 4:15 pm]

BILLING CODE 6735–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (''Act'') (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than June 19, 2019.

A. Federal Reserve Bank of Minneapolis (Mark A. Rauzi, Vice President), 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *The Dawn M. Van Vugt Revocable Living Trust (Dawn M. Van Vugt, trustee) and Timothy J. Van Vugt as co-trustee, both of Sioux Falls, South Dakota;* to join the Kooiman Family shareholder group, a group acting in concert, and acquire shares of First Rushmore, Bancorporation, Inc., Worthington, Minnestota and thereby indirectly acquire shares of First State Bank Southwest, Pipestone, Minnesota.

Board of Governors of the Federal Reserve System, May 29, 2019.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2019–11471 Filed 5–31–19; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

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

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than June 28, 2019.

A. Federal Reserve Bank of St. Louis (David L. Hubbard, Senior Manager) P.O. Box 442, St. Louis, Missouri 63166–2034. Comments can also be sent electronically to *Comments.applications@stls.frb.org:*

1. *Central Bancompany, Inc., Jefferson City, Missouri;* to acquire 100 percent of the voting shares of Liberty Bancorp, Inc., Liberty, Missouri, and thereby indirectly acquire BankLiberty, Liberty, Missouri.

B. Federal Reserve Bank of Minneapolis (Mark A. Rauzi, Vice President), 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *Plains Commerce Financial, Inc., Hoven, South Dakota;* to become a bank holding company by acquiring 100 percent of the voting shares of Plains Commerce Bank, Hoven, South Dakota.

C. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *Intrust Financial Corporation, Wichita, Kansas;* to merge with First Newton Bankshares, Inc., and thereby indirectly acquire First Bank of Newton, both in Newton, Kansas.

Board of Governors of the Federal Reserve System, May 29, 2019.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2019–11472 Filed 5–31–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice–MVC–2019–01; Docket No. 2019–0009; Sequence No. 1]

Federal Acquisition Regulation; Prohibition on Contracting With Entities Using Certain Telecommunications and Video Surveillance Services or Equipment (FAR Case 2019–009), Public Meeting

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

ACTION: Announcement of public meeting.

SUMMARY: DoD, GSA, and NASA are hosting a public meeting to obtain views of experts and interested parties regarding implementation of section 889 of Title VII of the NDAA for FY 2019, with specific focus on the implementation of paragraph (a)(1)(B). This paragraph prohibits agencies from entering into a contract (or extending or renewing a contract) with an entity that uses any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system.

DATES: The public meeting will be held on Friday, July 19, 2019, from 9:00 a.m. to 3:00 p.m., Eastern Daylight Time (EDT). The meeting will end prior to 3:00 p.m. if all speakers have concluded their presentations and there are no further comments from the general public.

ADDRESSES: The meeting will be held in the Department of Interior (DOI) Auditorium at 1849 C St. NW, Washington, DC 20240. Interested parties may also attend virtually through GSA's virtual meeting platform, hosted by Adobe Connect. DoD, GSA, and NASA cannot guarantee the reliability of the virtual meeting platform. Further details on the virtual meeting will be made available a few days before the meeting on the GSA Interact web page at *https://interact.gsa.gov/FY19NDAASection889*. Further information for the public meeting may be found under the heading **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Mr. Kevin Funk, Procurement Analyst, 202–357–5805.

SUPPLEMENTARY INFORMATION:

A. Background

The National Defense Authorization Act (NDAA) for Fiscal Year 2019 (Pub. L. 115–232), Title VII, Section 889, Prohibition on certain telecommunications and video surveillance services or equipment, identifies sources of ''covered telecommunications equipment or services'' and, in paragraph (a)(1)(B), states that ''The head of an executive agency may not enter into a contract (or extend or renew a contract) with an entity that uses any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system.''

DoD, GSA, and NASA are seeking feedback from stakeholders to inform effective implementation of the prohibition in paragraph (a)(1)(B). Paragraph (a)(1)(A) of section 889 will be implemented separately through FAR Case 2018–017.

Given the focus of section 889, it is anticipated that the impact of implementation of paragraph (a)(1)(B) may vary across affected stakeholder communities, including information and communications technology vendors, security services vendors, and other vendors who provide unrelated goods and services but rely on information and communications technology and security services as incidental but essential components of their operations.

As the Government considers implementation of section 889, DoD, GSA, and NASA especially welcome input on the following questions regarding anticipated impact on affected stakeholders:

- Beyond the statutory language of the prohibition, what additional information or guidance do you view as necessary to effectively comply with paragraph (a)(1)(B) of section 889?
- To what extent will compliance with the prohibition in paragraph (a)(1)(B) of section 889 incur additional cost or other burden in providing goods or services to the Federal government? Please be specific in describing the impact.
- To what extent do you currently have insight into existing systems and their components, sufficient to ensure compliance with paragraph (a)(1)(B) of section 889?
- To what extent do you currently have direct control over existing systems in use (*e.g.,* physical security systems) and their components, as contrasted with contracting for services that are provided by a separate entity (*e.g.,* landlords, subcontractors)?
- To the extent that there are gaps in insight or control described in response to the previous questions, how much time do you anticipate will be needed to establish the required insight or control to ensure compliance with paragraph (a)(1)(B) of section 889?
- Will the requirement to comply with the prohibition in paragraph (a)(1)(B) impact your willingness to offer goods and services to the Federal government as of the stated effective date? Please be specific in describing the impact (*e.g.,* what types of products or services might no longer be offered, or offered in a modified form, and why).
- To what extent does your response to the above question change if you are given more time?
- What other challenges do you anticipate facing in effectively meeting the implementation date of August 13, 2020?

B. Registration

To ensure adequate room accommodations and to facilitate security screening and entry to the DOI Auditorium, individuals wishing to attend the public meeting in-person must register by Friday, July 5, 2019. To register, please visit the GSA Interact web page at *https://interact.gsa.gov/FY19NDAASection889,* and utilize the in-person registration link provided. Registration for in-person attendance is free and based on space availability. Early registration is recommended because, registration will close once the capacity for the DOI Auditorium has been reached. Members of the press must also RSVP to *press@gsa.gov* by July 5, 2019.

C. In-Person Attendance

Registration check-in will begin at 8 a.m., EDT, on July 19, 2019, with the meeting starting promptly at 9 a.m., EDT. Information on getting to the DOI building can be found on *https://www.doi.gov/interiormuseum/Plan-a-Visit.* Attendees must be prepared to present a valid form of government-issued photo identification. There is no food or drink allowed in the DOI Auditorium. There is no parking available at DOI; however, there is public parking available nearby.

D. Format

DoD, GSA, and NASA intend to conduct a town-hall style discussion focused on implementation of paragraph (a)(1)(B) of section 889 of Title VII of the NDAA for FY 2019 (Pub. L. 115–232). In-person attendees will be provided an opportunity to provide prepared

comments and presentations during the discussion as time allows. Attendees participating through the virtual platform will only be able to join the meeting in a ''listen only'' mode and will not be able to provide prepared remarks or presentations. A copy of the agenda will be posted prior to the date of the meeting on the GSA Interact web page at *https://interact.gsa.gov/FY19NDAASection889*.

E. Presentations

If you wish to make a presentation, please submit an electronic copy of your presentation via email to *kevin.funk@gsa.gov* no later than Monday, July 8, 2019. Attendees providing presentations, including prepared comments, shall be limited to ten minutes. Each presentation should be in PowerPoint to facilitate projection during the public meeting and should include the presenter's name, organization affiliation, telephone number, and email address on the cover page.

Please submit presentations only and cite ''Public Meeting, FAR Case 2019–009'' in all correspondence related to the public meeting. There will be no transcription of the meeting. The submitted presentations will be the only record of the public meeting and will be posted at the conclusion of the public meeting to the GSA Interact web page at *https://interact.gsa.gov/FY19NDAASection889*.

F. Special Accommodations

The public meeting is physically accessible to people with disabilities. Request for sign language interpretation or other auxiliary aids should be directed to *kevin.funk@gsa.gov* by Monday, June 24, 2019. Please see the GSA Interact web page at *https://interact.gsa.gov/FY19NDAASection889* for additional information on public meeting content and for a posting of the agenda (to be made available a few days prior to the meeting).

Dated: May 29, 2019.

Janet Fry,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2019–11490 Filed 5–31–19; 8:45 am]

BILLING CODE 6820–EP–P

GENERAL SERVICES ADMINISTRATION

[Notice PBRB–2019–01; Docket No. GSA–GSA–2019–0012; Sequence No. 1]

Public Buildings Reform Board; Notice of Meeting

AGENCY: Public Buildings Reform Board.

ACTION: Notice of public meeting.

SUMMARY: As provided by the Federal Assets Sale and Transfer Act of 2016 (FASTA), the Public Buildings Reform Board (PBRB) is holding its first public meeting. At this meeting, the Board will hear from government and private sector representatives to gain their perspectives on implementation of FASTA and FASTA's opportunities and challenges.

DATES: The meeting is scheduled for Monday, June 17th, 2019, from 9:00 a.m. to 4:00 p.m. (Eastern Daylight Time).

ADDRESSES: General Services Administration (GSA), National Capital Region Headquarters Auditorium, 301 7th St. SW, Washington, DC 20407. The meeting is open to the public and the site is accessible to individuals with disabilities.

FOR FURTHER INFORMATION CONTACT: Interested participants can contact Ira Holmes, PBRB, by phone at 301–802–7274 or by email at *iholmes@bdo.com*.

SUPPLEMENTARY INFORMATION:

Background: FASTA created the PBRB as an independent Board to identify opportunities for the Federal government to significantly reduce its inventory of civilian real property and thereby reduce costs. The Board is directed, within 6 months of its formation, to recommend to the Office of Management and Budget (OMB) the sale of not fewer than five properties not on the list of surplus or excess with a fair market value of not less than $500 million and not more than $750 million. In two subsequent rounds over a five-year period, the Board is responsible for making recommendations for other sales, consolidations, property disposals or redevelopment of up to $7.25 billion.

Meeting: The format for the meeting will be panel discussions with appropriate time allowed for Q&A. Each panel will be composed of invited representatives for that specific area. The three proposed panels are:

- Executive Branch—this panel will include representatives from the Federal Property Council and the GSA Public Buildings Service. The purpose will be to provide a prospective on background of the legislation (FASTA) and the current status of the database.
- Congressional panel—this panel will discuss background and importance of legislation.
- Former RTC officials panel—this panel will discuss the RTC's approach to the large number of properties and methods of increasing the valuation for sale.

Portions of the meeting will be held in Executive Session if the Board is considering issues involving classified or proprietary information.

Registration: To register for this meeting, please email Ira Holmes at *iholmes@bdo.com*. Those wishing to participate as panelists are invited to contact the PBRB by June 10th, 2019. The PBRB especially invites former officials from the Resolution Trust Corporation (RTC) to participate on the panel to provide their insight. Individuals wishing to attend who require special assistance should contact Ira Holmes at least 72 hours prior to the event.

Lois Mandell,

Federal Register Liaison, General Services Administration.

[FR Doc. 2019–11492 Filed 5–31–19; 8:45 am]

BILLING CODE 3412–RT–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Proposed Collection; Comment Request; Older Americans Act, Title VI Grant Application

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing an opportunity for the public to comment on the proposed collection of information listed above. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice.

This notice solicits comments on the Proposed New Collection and solicits comments on the information collection requirements related to the Application for Older Americans Act, Title VI Parts A/B and C Grants.

DATES: Comments on the collection of information must be submitted

electronically by 11:59 p.m. (EST) or postmarked by August 2, 2019.

ADDRESSES: Submit electronic comments on the collection of information to: Rhonda Schwartz. Submit written comments on the collection of information to the Administration for Community Living, Washington, DC 20201, Attention: Rhonda Schwartz.

FOR FURTHER INFORMATION CONTACT: Rhonda Schwartz, Administration for Community Living, Washington, DC 20201, Rhonda Schwartz, *Rhonda.Schwartz@acl.hhs.gov,* (617) 565–1165.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. A Collection of information includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. The PRA 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, ACL is publishing a notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, ACL invites comments on our burden estimates or any other aspect of this collection of information, including:

(1) Whether the proposed collection of information is necessary for the proper performance of ACL's functions, including whether the information will have practical utility;

(2) the accuracy of ACL's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used to determine burden estimates;

(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.

ACL is responsible for administering the Title VI A/B (Nutrition and Supportive Service) and C (Caregiver) grants. The purpose of this data collection is to improve and standardize the format of the application. The instrument will collect data as prescribed by the Older Americans Act Section 612(a), 614(a) and 45 CFR 1326.19 related to the eligibility of Federally-recognized Tribes and Native Hawaiian organizations for grant funds under this program and their capacity to deliver services to elders.

The Application for Older Americans Act, Title VI A/B and C Grants collects information on the ability of federally-recognized American Indian, Alaskan Native and Native Hawaiian organizations to provide nutrition, supportive, and caregiver services to elders within their service area.

Applicants are required to provide a description of their organization's service area, the number of eligible elders in their service area, and their ability to deliver services and sign assurances that the organization will comply with all applicable laws and regulations.

This is a new data collection. In prior grant cycles, AoA used ACL's generic clearance for the funding opportunity announcement (FOA) information collection currently approved under OMB control number 0985–0018. The proposed data collection materials have been updated to better align with the requirements of the Older Americans Act and Federal regulations, as well as to improve data quality and grantee accountability. Furthermore, this grantee application will better line up with the revised Title VI Program Performance Report under 0985–0059 and will eliminate duplicate reporting requirements for grantees. This data collection will also support ACL in tracking performance outcomes and efficiency measures with respect to the annual and long-term performance targets established in compliance with the Government Performance Results Modernization Act (GPRMA).

The proposed data collection tools may be found on the ACL website for review at *https://www.acl.gov/about-acl/public-input.*

Estimated Program Burden: Title VI grant applications are required once every three (3) years, so an annual response is not required for this instrument (the annual burden below reflects this calculation). Additionally, Title VI funding is broken into three categories.

Parts A and B are for nutritional and supportive programming, with Part A being restricted to American Indian and Alaska Native grantees, and Part B restricted to Native Hawaiian grantees. Part C is for caregiver programming. All Part C grantees must have Part A/B funding, but not all Part A/B grantees will have Part C programs. Therefore, there are likely to be 295 unique respondents, but only 250 will have to complete all three portions of the application. This application covers all three parts of Title VI.

ACL estimates the burden associated with this collection of information as follows:

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Title VI Application Part A/B	295	1	2.75	270.4
Title VI Application Part C	250	1	1.5	125
Total			4.25	395.4

The number of burden hours associated with the Title VI, Part C, data collection was calculated as 811.25. However, since this instrument is used only once every 3 years, this number was annualized by dividing it into thirds. This resulted in an annualized number of 270.4 hours. Similarly, the total hours associated with the Title VI, Part C, application is 375. This number was annualized by dividing it by three, resulting in an annual burden hours of 125.

Dated: May 23, 2019.

Lance Robertson,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2019–11475 Filed 5–31–19; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Pain Management Best Practices Inter-Agency Task Force

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that a meeting via WebEx is scheduled to be held for the Pain Management Best Practices Inter-Agency Task Force (Task Force) with the HHS Centers for Medicaid & Medicare Services. This meeting will be open to the public via phone.

DATES: The Task Force meeting will be held on Wednesday, June 12, 2019 from 5 p.m. to 6:30 p.m. Eastern Time. The agenda will be posted on the Task Force website at *https://www.hhs.gov/ash/advisory-committees/pain/index.html*.

ADDRESSES: The virtual meeting will be accessible by phone. Information on how to join the meeting will be available on the Task Force website: *https://www.hhs.gov/ash/advisorycommittees/pain/index.html*.

FOR FURTHER INFORMATION CONTACT: Alicia Richmond Scott, Designated Federal Officer, Pain Management Best Practices Inter-Agency Task Force, U.S. Department of Health and Human Services, Office of the Assistant Secretary for Health, 200 Independence Avenue SW, Room 736E, Washington, DC 20201. Phone: 240–453–2816. Email: *paintaskforce@hhs.gov*.

SUPPLEMENTARY INFORMATION: Section 6032 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, Public Law 115–271 requires that the Secretary of Health and Human Services, by January 1, 2020, collaborate with the Pain Management Best Practices Inter-Agency Task Force (Task Force), to develop an action plan on recommendations for changes under Medicare and Medicaid to prevent opioids addictions and enhance access to Medication-Assisted Treatment. The Task Force, established under Section 101 of the Comprehensive Addiction and Recovery Act of 2016 (Pub. L. 114–198), is governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C. App), which sets forth standards for the formation and use of advisory committees.

The purpose of this meeting is for the Task Force to collaborate with HHS, Centers for Medicaid & Medicare Services in a virtual meeting, on June 12, 2019 to discuss payment and coverage policies for chronic and acute pain, service delivery models, access to therapies and medical devices, and other issues outlined in section 6032 of the SUPPORT Act. Information about the final meeting agenda will be posted prior to the meeting on the Task Force website: *https://www.hhs.gov/ash/advisorycommittees/pain/index.html*.

Members of the public are invited to listen by phone. Individuals who need special assistance should send an email to the Pain Task Force email address (*paintaskforce@hhs.gov*) and indicate the special accommodation. More information on joining the meeting can be found at *https://www.hhs.gov/ash/advisory-committees/pain/index.html*.

Written comments from the public will be accepted through the Federal eRulemaking Portal at *http://www.regulations.gov,* docket number HHS–OS–2019–0008.

Dated: May 28, 2019.

Vanila M. Singh,

Chief Medical Officer, Chair, Pain Management Task Force, Office of the Assistant Secretary for Health.

[FR Doc. 2019–11473 Filed 5–31–19; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Opportunity To Collaborate on National Youth Sports Initiative To Increase Youth Sports Participation

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health, Office of the President's Council on Sports, Fitness and Nutrition.

ACTION: Notice.

SUMMARY: The Office of the President's Council on Sports, Fitness and Nutrition (PCSFN) solicits requests from non-Federal public and private sector organizations and entities who wish to collaborate on the National Youth Sports Initiative (NYSI). NYSI collaboration projects will involve executing a singular or series of financially self-sustaining programs, activations, and/or activities that elevate the benefits and importance of youth sports participation and increase sports participation among girls, youth from racial and ethnic backgrounds, and/or youth with a disability. Potential collaborating organizations must have demonstrated interest in and experience with coordinating youth sports-focused activities, be capable of managing the day to day operations associated with the proposed activity, and be willing to participate substantively in the execution of the proposed activity, not just providing funding or logistical support.

DATES: To receive consideration, a request to participate as a collaborating organization must be received via email or postmarked mail at the addresses listed below, by 5:00 p.m. EST on Friday, June 7, 2019. Requests will meet the deadline if they are either (1) received on or before the deadline date; or (2) postmarked on or before the deadline date. Private metered postmarks will not be accepted as proof of timely mailing. Hand-delivered requests must be received by 5:00 p.m. EST on Friday, June 7, 2019. Requests that are received after the deadline will be returned to the sender.

ADDRESSES: Proposals for NYSI collaborations may be submitted via email to *Sports@hhs.gov*. Proposals may also be sent to Holli Richmond, Executive Director, President's Council on Sports, Fitness & Nutrition; 1101 Wootton Parkway, Suite 560, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Holli Richmond, President's Council on Sports, Fitness & Nutrition, Office of the Assistant Secretary for Health, HHS; 1101 Wootton Parkway, Suite 560, Rockville, MD 20852; Telephone (240) 276–9866. Email: *Sports@hhs.gov*.

SUPPLEMENTARY INFORMATION:

Background

PCSFN was established as the President's Council on Youth Fitness by President Eisenhower in 1956. PCSFN currently operates under Executive Order (E.O.) 13265, amended by E.O. 13824. The Council advises the President, through the Secretary, about progress to expand and encourage youth sports participation, to promote the overall physical fitness, health, and nutrition of all Americans. The Council is the only federal advisory committee focused solely on the promotion of physical activity, fitness, sports, and nutrition.

The Office of the PCSFN works with the President's Council and, under its authority in Title XVII of the Public Health Service Act, shares the President's Council's mission to engage, educate, and empower all Americans to adopt a healthy lifestyle that includes regular physical activity and good nutrition. Through partnerships with the public, private, and non-profit sectors, the Office of the PCSFN

promotes programs and initiatives that motivate people of all ages, backgrounds, and abilities to lead active, healthy lives. The Office of the PCSFN is authorized, in conjunction with its Title XVII authorities, under section 2 of E.O. 13824 to develop a National Youth Sports Initiative (NYSI). Specifically the E.O. states, ''The Secretary of Health and Human Services (Secretary), in carrying out the Secretary's responsibilities for public health and human services, shall develop a national strategy to expand children's participation in youth sports, encourage regular physical activity, including active play, and promote good nutrition for all Americans.'' The purpose of the NYSI is to elevate the importance of youth sports participation, as well as to increase sports participation among youth with below-average sports participation, including girls, youth with a disability or those from racial and ethnic backgrounds; as well as youth in communities with limited access to athletic facilities or recreational areas. The Office of the PCSFN solicits proposals from non-Federal private and public stakeholders who wish to collaborate on the NYSI by planning and executing sport programs, activations, and/or other activities that expand access for and inclusion of youth with below-average sports participation or those from economically distressed areas.

Requirements of the Collaboration

The Office of the PCSFN is seeking organizations capable of managing the development and execution of youth sports programs, activations and/or other activities (such as awareness campaigns), and identifying ways to enhance activities and participation. Approved proposals will require a co-sponsorship signed by both participants that outlines the terms and parameters of the agreement. The co-sponsorship will be in place for a period of one year from the date at which it bears all parties' signatures.

NYSI Projects

Proposed NYSI projects will develop and implement sport-focused programming, activations, and/or other activities that are evidence-based and result in sustainable strategies that encourage and engage youth in a range of physical activity through sports participation before, during or after the school day. The collaborating organization shall help promote the project through outreach activities that may include using social media, exhibiting at conferences, or speaking at events. The collaborating organization shall identify and recommend ways to enhance delivery and outreach of the youth sports program/activation/activity. Upon signing the above referenced co-sponsorship, and as long as the program/activation/activity meets all requirements, the Office of the PCSFN will grant collaborating organizations the use of its logo and NYSI-branded materials to promote the project, and will highlight the NYSI project via its digital and social media platforms, as deemed appropriate. Use of Office of the PCSFN logo and NYSI-branded materials should not imply any Federal endorsement of the collaborating organization's general policies, activities, or products.

Eligibility for Collaborating Organizations

To be eligible, a requester shall: (1) Have a demonstrated interest in, understanding of, and experience with managing the development and execution of fun and engaging youth sports programs, activations and/or other activities related to promoting the benefits and importance of youth sports participation; (2) participate substantively in the proposed NYSI project (not just provide funding or logistical support); (3) have an organizational or corporate mission that is aligned with the mission of PCSFN and the Department; and (4) agree to sign a co-sponsorship with the Office of the PCSFN which will set forth the details of the NYSI project activity including the requirements that any fees raised should not exceed the collaborating organization's costs, and fees collected by the collaborating organization shall be limited to the amount necessary to cover the collaborating organization's related operating expenses. Collaborating organizations are solely responsible for collecting and handling any fees to cover their costs.

The collaborating organization shall furnish the necessary personnel, materials, services, and facilities to administer the proposed NYSI project. These duties will be determined and outlined in a co-sponsorship.

Collaborating Organization Proposal

Each collaborating organization's proposal shall contain a description of: (1) The entity or organization; (2) its background in managing the development and execution of fun and engaging youth sports programs, activations and/or other activities related to promoting the benefits and importance of youth sports participation; (3) its proposed involvement in the NYSI project; and (4) the proposed project implementation plan with a timeline.

Evaluation criteria: The Office of the PCSFN will select the NYSI projects using the following evaluation criteria:

(1) Requester's qualifications and capability to fulfill proposed NYSI project responsibilities;

(2) Requester's creativity in developing and executing the proposed project, including the variety of sport activities offered and the medium through which participants are recruited and project messages are delivered;

(3) Requester's proposed plan and potential for reaching youth with below-average sports participation or those from economically distressed areas, including girls, youth with a disability, and those from racial and ethnic backgrounds;

(4) Requester's experience administering national, state and/or local youth sports or physical activity programs, activations and/or activities that have successfully increased youth sports participation or awareness of the benefits and importance of youth sports participation;

(5) Requester's past or current work specific to programs, activations and/or activities in the area(s) of sports participation among youth with below-average sports participation or those from economically distressed areas;

(6) Requester's personnel: Name, professional qualifications and specific expertise of key personnel who would be available to work on the NYSI project;

(7) Requester's facilities and infrastructure: Availability and description of facilities or other infrastructure necessary to develop and execute the programs, activations and/or activities, including sport fields, recreational spaces, office space and information technology and telecommunication resources;

(8) Requester's description of financial management: Discussion of experience in developing a project budget and collecting and managing monies from organizations and individuals;

(9) Requester's proposed plan for managing the NYSI project, including such aspects as participant recruitment, website development and/or enhancement, cost of materials, and distribution of those items.

Dated: May 20, 2019.

Holli Richmond,

Executive Director, President's Council on Sports, Fitness, and Nutrition, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services.

[FR Doc. 2019–11476 Filed 5–31–19; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; The Clinical Trials Reporting Program (CTRP) Database (NCI)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Gisele Sarosy, MD, Coordinating Center for Clinical Trials (CCCT), National Cancer Institute, 9609 Medical Center Drive, 6W134, Rockville, MD 20852 or call non-toll-free number 240–276–6172 or Email your request, including your address to: *gisele.sarosy@nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: The Clinical Trials Reporting Program (CTRP) Database, 0925–0600, Expiration Date 08/31/2019—EXTENSION, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The Clinical Trials Reporting Program (CTRP) Database is an electronic resource that serves as a single, definitive source of information about all NCI-supported clinical research. This resource allows the NCI to consolidate reporting, aggregate information and reduce redundant submissions. Information is submitted by clinical research administrators as designees of clinical investigators who conduct NCI-supported clinical research. The designees can electronically access the CTRP website to complete the initial trial registration. Subsequent to registration, four amendments and four study subject accrual updates occur per trial annually.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The estimated annualized burden hours are 18,000.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondents	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hours
Initial Registration	Clinical Trials	3,000	1	1	3,000
Amendment.		1,500	4	1	6,000
Update.		1,500	4	1	6,000
Accrual Updates.		3,000	4	15/60	3,000
Total		9,000	27,000		18,000

Patricia M. Busche,

Project Clearance Liaison, National Cancer Institute, National Institutes of Health.

[FR Doc. 2019–11459 Filed 5–31–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Generic Clearance for Application Information for Fellowships, Internships, Training Programs, and Specialty Positions, National Cancer Institute (NCI)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by

fax to 202–395–6974, Attention: Desk Officer for NIH.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Vivian Horovitch-Kelley, Program Analyst, Office of Management Policy and Compliance, National Cancer Institute, 9609 Medical Center Drive, Room 2W444, Bethesda, Maryland 20892 or call non-toll-free number (240) 276–6850 or Email your request, including your address to: *vivian.horovitch-kelley@mail.nih.gov*.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on March 29 (Vol. 84, No. 61, Page 11987) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute (NCI), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: Generic Clearance for Application Information from Fellows, Interns, and Trainees, 0925–XXXX, Exp., Date XX/XXXX, NEW, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: This is a new generic information collection request to support the science and research in a multidisciplinary environment at the National Cancer Institute (NCI), a part of the National Institutes of Health. Applicants may possess a variety of degrees including, but not limited to, high school, post-baccalaureate, graduate, postdoctoral, Registered Nurse, and Doctor of Medicine (MD). Potential applicants may apply for cancer-related positions by submitting applications, resumes, curriculum vitae (CV), reference letters, letters of intent and interest, and other related documentation directly to the Divisions, Offices, and Centers. This information is necessary to evaluate the eligibility, merits, and quality of potential candidates and will also assist in matching potential candidates to various training and internship programs, and specialty positions. The information is for internal use to make decisions about candidates invited to visit and attend NCI fellowships, internships, training opportunities, and apply for specialized staff and faculty positions.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden is 15,000 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hours
Individuals (Applicants)	6,000	1	60/60	6,000
Individuals (Professional References)	18,000	1	30/60	9,000
Totals	24,000	24,000	.....	15,000

Patricia M. Busche,

Project Clearance Liaison, National Cancer Institute, National Institutes of Health.

[FR Doc. 2019–11461 Filed 5–31–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

All of Us Research Program, Tribal Consultation Meetings and Listening Sessions

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) *All of Us* Research Program will host four Tribal Consultations to consult on the best practices for engaging with Tribal Nations to facilitate the inclusion of American Indian and Alaska Native (AI/AN) populations in this program. They will take place at three U.S. Department of Health and Human Services (HHS) Regional Consultations and at the National Congress of American Indians (NCAI) Mid-Year Conference and Marketplace.

DATES:

June 18, 2019: HHS Regional Consultation, Region 9 (Sacramento, CA).

June 24, 2019: NCAI Mid-Year Conference & Marketplace (Sparks, NV).

August 21, 2019: HHS Regional Consultation, Regions 1–4 (Washington, DC).

August 21, 2019: HHS Regional Consultation, Regions 6–8 (Denver, CO).

ADDRESSES: A full schedule of consultations with specific dates and times, as well as full location information, will be made available at *https://AllofUs.nih.gov/All-Us-Tribal-Engagement*.

FOR FURTHER INFORMATION CONTACT: The *All of Us* Tribal Engagement team by phone at 240–515–5317, by email at *AOUTribal@nih.gov,* or by mail at 6011 Executive Boulevard, Suite 214, Rockville, MD 20852.

SUPPLEMENTARY INFORMATION: In accordance with the U.S. Department of Health and Human Services' (HHS) Tribal Consultation Policy, *All of Us* announces that they will be holding four Tribal consultations during summer 2019: at the HHS Regional Consultation in Sacramento, California on June 18; at the NCAI Mid-Year Conference & Marketplace in Sparks, Nevada on June 24; at the HHS Regional Consultation in Washington, DC on July 16; and at the HHS Regional Consultation in Denver, Colorado on August 21.

The *All of Us* Research Program aims to accelerate health research and medical breakthroughs to enable an era of precision medicine for all. *All of Us* is committed to ensuring the program reflects the diversity of the United States. The goal for these events is to facilitate information exchange and provide an opportunity for Tribal and Urban Indian Organization leadership to have meaningful input as *All of Us* identifies priorities and opportunities around the inclusion of AI/AN

populations in the research program while also implementing the appropriate protections to comply with Tribal research oversight and laws. *All of Us* will also host listening sessions throughout summer 2019. A full schedule of consultations and listening sessions will be made available on the *All of Us* Tribal Engagment web page at *https://AllofUs.nih.gov/All-Us-Tribal-Engagement*.

Dated: May 28, 2019.

Lawrence A. Tabak,

Principal Deputy Director, National Institutes of Health.

[FR Doc. 2019–11494 Filed 5–31–19; 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; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Child Health and Human Development Special Emphasis Panel, which was published in the **Federal Register** on February 28, 2019, 84 FR 6808.

The meeting date has changed from a two-day meeting on June 27th and June 28th, 2019 to a one day meeting on June 28th, 2019. The meeting is closed to the public.

Dated: May 28, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–11437 Filed 5–31–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Draft NTP Technical Reports on Prenatal Developmental Toxicity Studies; Availability of Documents; Request for Comments; Notice of Peer-Review Meeting

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Toxicology Program (NTP) announces the availability of four draft NTP Technical Reports on prenatal developmental toxicity studies scheduled for peer-review for the following substances: Tris(chloropropyl) phosphate, 4-methylcyclohexanemethanol, vinpocetine, and dimethylaminoethanol bitartrate. The peer-review meeting is open to the public. Registration is required for in-person meeting attendance, oral comment, and to access the webcast. Information about the meeting and registration is available at *https://ntp.niehs.gov/go/36051*.

DATES:

Meeting: July 31, 2019, 8:30 a.m. to adjournment at approximately 5:00 p.m. Eastern Daylight Time (EDT). The meeting may end earlier or later than 5:00 p.m. EDT.

Document Availability: The four draft NTP Technical Reports should be available by June 5, 2019, at *https://ntp.niehs.gov/go/36051*.

Written Public Comment Submissions: Deadline is July 17, 2019.

Registration for Oral Comments: Deadline is July 17, 2019.

Registration to Attend Meeting In-Person: Deadline is July 17, 2019.

Registration to View Webcast: Deadline is July 31, 2019.

ADDRESSES:

Meeting Location: Conference Room F193, Rall Building, NIEHS, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

Meeting web page: The draft reports, preliminary agenda, registration, and other meeting materials will be available at *https://ntp.niehs.gov/go/36051*.

Webcast: The URL for viewing the peer-review meeting webcast will be provided to registrants.

FOR FURTHER INFORMATION CONTACT:

Email *NTP-Meetings@icf.com*. Dr. Elizabeth Maull, NIEHS/DNTP, is the Designated Federal Official. Phone: (984) 287–3157, Fax: (301) 480–3008. Email: *maull@niehs.nih.gov*.

SUPPLEMENTARY INFORMATION:

Meeting Attendance Registration: The meeting is open to the public with time set aside for oral public comment. As meeting space at NIEHS is under renovation, very limited space is available for in-person attendance (~15 attendees). Registration for in-person attendance is on a first-come, first-served basis. After maximum capacity is reached, persons will be placed on a wait list and notified should an opening become available. Registration to attend the meeting in person is by July 17, 2019, at *https://ntp.niehs.gov/go/36051* and for the webcast is July 31, 2019, at *https://ntp.niehs.gov/go/36051*. The URL for the webcast will be provided in the email confirming registration. Visitor and security information for those attending in person is available at *https://www.niehs.nih.gov/about/visiting/index.cfm*. Individuals with disabilities who need accommodation to view the webcast should contact Susan Blaine by phone: (703) 225–2471 or email: *NTP-Meetings@icf.com*. TTY users should contact the Federal TTY Relay Service at (800) 877–8339. Requests should be made at least five business days in advance of the event.

Request for Comments: NTP invites written and oral public comments on the draft reports that address scientific or technical issues. Guidelines for public comments are at *https://ntp.niehs.nih.gov/ntp/about_ntp/guidelines_public_comments_508.pdf*.

The deadline for submission of written comments is July 17, 2019, to enable review by the peer-review panel and NTP staff prior to the meeting. Written public comments should be submitted through the meeting website at *https://ntp.niehs.gov/go/36051*. Persons submitting written comments should include name, affiliation, mailing address, phone, email, and sponsoring organization (if any). Written comments received in response to this notice will be posted on the NTP website and the submitter will be identified by name, affiliation, and sponsoring organization (if any). Comments that address scientific or technical issues will be forwarded to the peer-review panel and NTP staff prior to the meeting.

Oral public comment at this meeting is welcome, with time set aside for the presentation of oral comments on the draft reports. The agenda allows for four public comment periods—one comment period per report (up to 6 commenters, up to 5 minutes per speaker, per report). Persons wishing to make an oral comment are required to register online at *https://ntp.niehs.gov/go/36051* by July 17, 2019, and indicate whether they will present comments in-person or via the teleconference line. Registration is on a first-come, first served basis. Each organization is allowed one time slot per report. The access number for the teleconference line will be provided to registrants by email prior to the meeting. Commenters will be notified approximately one week before the peer-review meeting about the actual time allotted per speaker.

If possible, oral public commenters should send a copy of their slides and/or statement or talking points to Susan Blaine by email: *NTP-Meetings@icf.com* by July 17, 2019. Written statements can supplement and may expand the oral presentation.

Meeting Materials: The draft NTP technical reports and preliminary agenda will be available on the NTP website at *https://ntp.niehs.gov/go/36051* prior to the meeting. NTP expects

that the draft reports should be available on the website by June 5, 2019. Additional information will be posted when available or may be requested in hardcopy from Susan Blaine by phone: (703) 225–2471 or email: *NTP-Meetings@icf.com*. Individuals are encouraged to access the meeting web page to stay abreast of current information regarding the meeting.

Following the meeting, a report of the peer-review will be prepared and made available on the NTP website.

Background Information on NTP Peer-Review Panels: NTP panels are technical, scientific advisory bodies established on an ''as needed'' basis to provide independent scientific peer-review and advise NTP on agents of public health concern, new/revised toxicological test methods, or other issues. These panels help ensure transparent, unbiased, and scientifically rigorous input to the program for its use in making credible decisions about human hazard, setting research and testing priorities, and providing information to regulatory agencies about alternative methods for toxicity screening. NTP welcomes nominations of scientific experts for upcoming panels. Scientists interested in serving on an NTP panel should provide their current curriculum vitae to Susan Blaine by email: *NTP-Meetings@icf.com*.

The authority for NTP panels is provided by 42 U.S.C. 217a; section 222 of the Public Health Service Act, as amended. The panel is governed by the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

This peer review is being conducted by a panel in attendance at NIEHS. Peer-review of future draft reports will be conducted in accordance with Department of Health and Human Services peer-review policies (*https://aspe.hhs.gov/hhs-information-quality-peer-review*) and Office of Management and Budget's Final Information Quality Bulletin for Peer Review (70 FR 2664, January 4, 2005).

Dated: May 21, 2019.

Brian R. Berridge,

Associate Director, National Toxicology Program.

[FR Doc. 2019–11463 Filed 5–31–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed 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 Child Health and Human Development Special Emphasis Panel; ZHD1 DSR–A (50).

Date: July 12, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda Downtown, 7335 Wisconsin Ave., Bethesda, MD 20814.

Contact Person: Rita Anand, Ph.D., Scientific Review Officer, Division of Scientific Review, National Institute of Child Health and Human Development, NIH, 6710B Rockledge Drive, Bethesda, MD 20892, 301–496–1487, *anandr@mail.nih.gov*.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; NIH Infant and Toddler Toolbox.

Date: July 25, 2019.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6710 B Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Sathasiva B. Kandasamy, Ph.D. Scientific Review Officer, Division of Scientific Review, National Institute of Child Health and Human Development, 6710B Rockledge Drive, Bethesda, MD 20892–9304, (301) 435–6680, *skandasa@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: May 28, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–11438 Filed 5–31–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Center for Cancer Training (CCT) Application Form for Electronic Individual Development Plan (eIDP) (National Cancer Institute)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: Desk Officer for NIH.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Erika Ginsburg, Scientific Program Analyst, Center for Cancer Training, National Cancer Institute, 9609 Medical Center Drive, Room 2W–106, Bethesda, Maryland 20892 or call non-toll-free number (240) 276–5627 or Email your request, including your address to: *ginsbure@mail.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on March 15, 2019, page 9537 (Vol. No. 84 FR 9537 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute (NCI), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: Center for Cancer Training (CCT) Application Form for electronic Individual Development Plan (eIDP), 0925–XXXX, Exp., Date XX/XXXX, NEW, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The National Cancer Institute's (NCI) Center for Cancer Training (CCT) supports NCI's goal of training cancer researchers with various educational levels (postbaccalaureate, graduate students, postdoctoral fellows) and for varying periods of time (3 months to 5 years). The eIDP is an online, detailed questionnaire focused on responses to career and professional goals and expectations while the trainee works at the NCI. The eIDP ensures the NCI trainees are receiving proper career and professional guidance, making appropriate progress, and determining activities to achieve their goals. The eIDP is also used to track trainees' career and professional goals and to ensure trainees receive the tools needed to achieve those goals. It is expected the trainees will complete the eIDP annually and that the eIDP process could be improved by their responses. The effectiveness of training could also be enhanced by the reports received by the trainees completing the eIDP. Individual Development Plans have been collected by paper and pencil from trainees since 2001. With the implementation of the electronic system, a pilot of the eIDP was approved by OMB (#0925–0046) and implemented in December 2018. The pilot improved the clarity of the instructions for the eIDP system, and incorporated feedback from the trainees to improve the overall trainee IDP experience, which advances the effectiveness of training

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden are 1,209 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hours
Individuals—Trainees	1,000	1	1	1,000
Individuals—Alumni	500	1	5/60	42
Individuals—Feedback	500	1	20/60	167
Totals	1,000	1,000		1,209

Patricia M. Busche,

Project Clearance Liaison, National Cancer Institute, National Institutes of Health.

[FR Doc. 2019–11460 Filed 5–31–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of HHS-Certified Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice

SUMMARY: The Department of Health and Human Services (HHS) notifies federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITF) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines).

A notice listing all currently HHS-certified laboratories and IITFs is published in the **Federal Register** during the first week of each month. If any laboratory or IITF certification is suspended or revoked, the laboratory or IITF will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory or IITF has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end and will be omitted from the monthly listing thereafter.

This notice is also available on the internet at *http://www.samhsa.gov/workplace*.

FOR FURTHER INFORMATION CONTACT: Charles LoDico, Division of Workplace Programs, SAMHSA/CSAP, 5600 Fishers Lane, Room 16N02C, Rockville, Maryland 20857; 240–276–2600 (voice).

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services (HHS) notifies federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITF) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 19644); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); April 30, 2010 (75 FR 22809); and on January 23, 2017 (82 FR 7920).

The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71. The ''Mandatory Guidelines for Federal Workplace Drug Testing Programs,'' as amended in the revisions listed above, requires strict standards that laboratories and IITFs must meet in order to conduct drug and specimen validity tests on urine specimens for federal agencies.

To become certified, an applicant laboratory or IITF must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory or IITF must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories and IITFs in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines. A HHS-certified laboratory or IITF must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA), which attests that it has met minimum standards.

In accordance with the Mandatory Guidelines dated January 23, 2017 (82 FR 7920), the following HHS-certified laboratories and IITFs meet the minimum standards to conduct drug

and specimen validity tests on urine specimens:

HHS-Certified Instrumented Initial Testing Facilities

Dynacare, 6628 50th Street NW, Edmonton, AB Canada T6B 2N7, 780–784–1190, (Formerly: Gamma-Dynacare Medical Laboratories).

HHS-Certified Laboratories

ACM Medical Laboratory, Inc., 160 Elmgrove Park, Rochester, NY 14624, 844–486–9226.

Alere Toxicology Services, 1111 Newton St., Gretna, LA 70053, 504–361–8989/800–433–3823, (Formerly: Kroll Laboratory Specialists, Inc., Laboratory Specialists, Inc.).

Alere Toxicology Services, 450 Southlake Blvd., Richmond, VA 23236, 804–378–9130, (Formerly: Kroll Laboratory Specialists, Inc., Scientific Testing Laboratories, Inc.; Kroll Scientific Testing Laboratories, Inc.).

Baptist Medical Center-Toxicology Laboratory, 11401 I–30, Little Rock, AR 72209–7056, 501–202–2783 (Formerly: Forensic Toxicology Laboratory Baptist Medical Center).

Clinical Reference Laboratory, Inc., 8433 Quivira Road, Lenexa, KS 66215–2802, 800–445–6917.

Cordant Health Solutions, 2617 East L Street, Tacoma, WA 98421, 800–442–0438 (Formerly: STERLING Reference Laboratories).

Desert Tox, LLC, 10221 North 32nd Street, Suite J, Phoenix, AZ 85028, 602–457–5411.

DrugScan, Inc., 200 Precision Road, Suite 200, Horsham, PA 19044, 800–235–4890.

Dynacare *, 245 Pall Mall Street, London, ONT, Canada N6A 1P4, 519–679–1630 (Formerly: Gamma-Dynacare Medical Laboratories).

ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655, 662–236–2609.

Laboratory Corporation of America Holdings, 7207 N. Gessner Road, Houston, TX 77040, 713–856–8288/800–800–2387.

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908–526–2400/800–437–4986 (Formerly: Roche Biomedical Laboratories, Inc.).

Laboratory Corporation of America Holdings, 1904 TW Alexander Drive, Research Triangle Park, NC 27709, 919–572–6900/800–833–3984 (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group).

Laboratory Corporation of America Holdings, 1120 Main Street, Southaven, MS 38671, 866–827–8042/800–233–6339 (Formerly: LabCorp Occupational Testing Services, Inc.; MedExpress/National Laboratory Center).

LabOne, Inc. d/b/a Quest Diagnostics, 10101 Renner Blvd., Lenexa, KS 66219, 913–888–3927/800–873–8845 (Formerly: Quest Diagnostics Incorporated; LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.).

MedTox Laboratories, Inc., 402 W. County Road D, St. Paul, MN 55112, 651–636–7466/800–832–3244.

Legacy Laboratory Services—MetroLab, 1225 NE 2nd Ave., Portland, OR 97232, 503–413–5295/800–950–5295.

Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, MN 55417, 612–725–2088, Testing for Veterans Affairs (VA) Employees Only.

Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311, 800–328–6942 (Formerly: Centinela Hospital Airport Toxicology Laboratory).

Pathology Associates Medical Laboratories, 110 West Cliff Dr., Spokane, WA 99204, 509–755–8991/800–541–7891x7.

Phamatech, Inc., 15175 Innovation Drive, San Diego, CA 92128, 888–635–5840.

Quest Diagnostics Incorporated, 1777 Montreal Circle, Tucker, GA 30084, 800–729–6432 (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories).

Quest Diagnostics Incorporated, 400 Egypt Road, Norristown, PA 19403, 610–631–4600/877–642–2216 (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories).

Redwood Toxicology Laboratory, 3700 Westwind Blvd., Santa Rosa, CA 95403, 800–255–2159.

US Army Forensic Toxicology Drug Testing Laboratory, 2490 Wilson St., Fort George G. Meade, MD 20755–5235, 301–677–7085, Testing for Department of Defense (DoD) Employees Only.

Charles P. LoDico,

Chemist.

[FR Doc. 2019–11450 Filed 5–31–19; 8:45 am]

BILLING CODE 4160–20–P

* The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. HHS, with the HHS' NLCP contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

Upon finding a Canadian laboratory to be qualified, HHS will recommend that DOT certify the laboratory (**Federal Register**, July 16, 1996) as meeting the minimum standards of the Mandatory Guidelines published in the **Federal Register** on January 23, 2017 (82 FR 7920). After receiving DOT certification, the laboratory will be included in the monthly list of HHS-certified laboratories and participate in the NLCP certification maintenance program.

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7011–N–22]

30-Day Notice of Proposed Information Collection: Low Income Housing Tax Credit Database

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 30 days of public comment.

DATES: *Comments Due Date:* July 3, 2019.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806, Email: *OIRA Submission@omb.eop.gov*.

FOR FURTHER INFORMATION CONTACT: Anna P. Guido, Reports Management Officer, QMAC, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Anna P. Guido at *Anna.P.Guido@hud.gov* or telephone 202–402–5535. This is not a toll-free number. Person with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. Copies of available documents

submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on Monday, February 11, 2019 at 84 FR 3222. The 60-day notice contained the old number 2528–0165 which was discontinued, however the new number is in this notice.

A. Overview of Information Collection

Title of Information Collection: Low Income Housing Tax Credit Database.

OMB Approval Number: 2528–0320.

Type of Request: Revision of a currently approved collection.

Form Number: HUD–52695 (HUD LIHTC Database Data Collection Form); HUD–52697 (HUD LIHTC Tenant Data Collection Form).

Description of the need for the information and proposed use: Section 2835(d) of the Housing and Economic Recovery Act, or HERA, (Pub. L. 110–289, approved July 30, 2008) amends Title I of the U.S. Housing Act of 1937 (42 U.S.C. 1437 *et seq.*) (1937 Act) to add a new section 36 (codified as 42 U.S.C. 1437z–8) that requires each state agency administering tax credits under section 42 of the Internal Revenue Code of 1986 (low-income housing tax credits or LIHTC) to furnish HUD, not less than annually, information concerning the race, ethnicity, family composition, age, income, use of rental assistance under section 8(o) of the U.S. Housing Act of 1937 or other similar assistance, disability status, and monthly rental payments of households residing in each property receiving such credits through such agency.

New section 36 requires HUD to establish standards and definitions for the information to be collected by state agencies and to provide states with technical assistance in establishing systems to compile and submit such information and, in coordination with other federal agencies administering housing programs, establish procedures to minimize duplicative reporting requirements for properties assisted under multiple housing programs.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
Tenant Data Form HUD–52697	60.00	1.00	60.00	40.00	2,400.00	$41.25	$99,000.00
Project Data Form HUD–52695	60.00	1.00	60.00	8.00	480.00	41.25	19,800.00
Total	120.00			48.00	2,880.00		118,800.00

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) 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) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: May 23, 2019.

Anna P. Guido,

Department Reports Management Officer Office of the Chief Information Officer.

[FR Doc. 2019–11511 Filed 5–31–19; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7011–N–19]

30-Day Notice of Proposed Information Collection: Notice of Application for Designation as a Single-Family Foreclosure Commissioner

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 30 days of public comment.

DATES: *Comments Due Date:* July 3, 2019.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax:202–395–5806, Email: *OIRA Submission@omb.eop.gov*.

FOR FURTHER INFORMATION CONTACT: Anna P. Guido, Reports Management Officer, QMAC, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Anna P. Guido at *Anna.P.Guido@hud.gov* or telephone 202–402–5535. This is not a toll-free number. Person with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on Wednesday, March 27, 2019 at 84 FR 11553.

A. Overview of Information Collection

Title of Information Collection: Notice of Application for Designation As a Single Family Foreclosure

Commissioner (SF Mortgage Foreclosure Act of 1994).

OMB Approval Number: 2510–0012.

Type of Request: Reinstatement of a currently approved collection.

Description of the need for the information and proposed use: Under the Single-Family Mortgage Foreclosure Act of 1994, HUD may exercise a nonjudicial Power of Sale of single-family HUD-held mortgages and may appoint Foreclosure Commissioners to do this. HUD needs the Notice and resulting applications for compliance with the Act's requirements that commissioners be qualified. Most respondents will be attorneys, but anyone may apply.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
Application for Foreclosure Commissioner	30.00	1.00	30.00	.50	15.00	$25.00	$375.00

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) 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) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: May 8, 2019.

Anna P. Guido,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2019–11510 Filed 5–31–19; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0027852; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Fowler Museum at University of California Los Angeles, Los Angeles, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Fowler Museum at University of California Los Angeles (UCLA) has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and associated funerary objects and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to the Fowler Museum at UCLA. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to the Fowler Museum at UCLA at the address in this notice by July 3, 2019.

ADDRESSES: Wendy G. Teeter, Ph.D., Fowler Museum at UCLA, Box 951549, Los Angeles, CA 90095–1549, telephone (310) 825–1864, email *wteeter@arts.ucla.edu*.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the Fowler Museum at University of California Los Angeles, Los Angeles, CA. The human remains and associated funerary objects were removed from an unknown site identified only as ''Zuni''.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Fowler Museum professional staff in consultation with representatives of the Zuni Tribe of the Zuni Reservation, New Mexico.

History and Description of the Remains

At an unknown time, human remains representing, at minimum, two individuals were removed from an unknown site, identified by the donor only as ''Zuni.'' Fowler Museum at UCLA received a large donation in 1966 and 1969 from Mr. W. Thomas Davis, Oxnard Farmlands. This donation included many southwestern objects, including several Zuni ''fetish bowls.'' One of them included fragmentary human remains representing a minimum number of two individuals. No known individuals were identified. There were 18 objects included with the human remains in a sealed bag. They include 10 pieces of plant stems, one corn cob, three ceramic sherds, two turquoise fragments, and two obsidian projectile points.

The human remains and associated funerary objects are Zuni based on the information provided by the donor on the donation inventory, as well as independent verification that the associated funerary objects are consistent with Zuni cultural traditions.

Determinations Made by the Fowler Museum at University of California Los Angeles

Officials of the Fowler Museum at University of California Los Angeles have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of two individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the 18 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects and the Zuni Tribe of the Zuni Reservation, New Mexico.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Wendy G Teeter, Ph.D., Fowler Museum at UCLA, Box 951549, Los Angeles, CA 90095–1549, telephone (310) 825–1864, email *wteeter@arts.ucla.edu,* by July 3, 2019. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects and the Zuni Tribe of the Zuni Reservation, New Mexico may proceed.

The Fowler Museum at University of California Los Angeles is responsible for notifying the Zuni Tribe of the Zuni Reservation, New Mexico that this notice has been published.

Dated: May 3, 2019.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2019–11430 Filed 5–31–19; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0027842; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: Eiteljorg Museum of American Indians and Western Art, Indianapolis, IN

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Eiteljorg Museum of American Indians and Western Art (Eiteljorg Museum), in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, has determined that the cultural items listed in this notice meet the definition of unassociated funerary objects. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request to the Eiteljorg Museum. If no additional claimants come forward, transfer of control of the cultural items to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to the Eiteljorg Museum at the address in this notice by July 3, 2019.

ADDRESSES: John Vanausdall, President/CEO, Eiteljorg Museum of American Indians and Western Art, 500 W Washington Street, Indianapolis, IN 46204, telephone (317) 275–1313, email *jvanasudall@eiteljorg.com.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items under the control of the Eiteljorg Museum of American Indians and Western Art, Indianapolis, IN, that meet the definition of unassociated funerary objects under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural items. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Items

In the mid-to late nineteenth century, four cultural items were removed from undisclosed sites in unknown counties in southeastern Alaska. Documentation regarding their removal and/or subsequent transfers prior to their accession into the Eiteljorg Museum's collection is limited. Preceding the foundation of the Eiteljorg Museum, in June 1989, by Harrison Eiteljorg, these four cultural items were part of the personal collection of Harrison Eiteljorg. The four cultural items are one Oyster Catcher Rattle, one Shaman's staff, one Clan or Shaman's Hat, and one Grave Guardian or Shaman Spirit Helper.

According to museum records, each of these four cultural items are identified as Tlingit. The Oyster Catcher Rattle was previously owned by John A. Buxton of Shango Galleries, and was purchased by Harrison Eiteljorg in November 15, 1979. The rattle, dated circa 1870, is constructed from a single piece of wood, bears black, red, and light blue pigments. It has been halved and likely hollowed out to hold what may be seeds used to create its rattling sound. A leather cord is tied at one side of the rattle. The top of the rattle represents a long-billed bird. Near the handle is a wolf spirit with a protruding tongue. The underside is carved to depict what may be a hawk. The Shaman's Staff, dated circa 1880, was purchased by Harrison Eiteljorg from Tom Julian, in June 1980. It was originally owned by Howard Roloff. It is made of carved wood, the top of which is ornamented with a killer whale design. The Shaman's Hat, dated circa 1800, in the form of a raven on top and a frog on the front, is constructed out of wood, semi-tanned hide, iron or copper alloy, fur, sinew, and paint. It was purchased by Harrison Eiteljorg from Sotheby's, Parke-Bernet in April 1981. The Shaman Spirit Helper, dated circa 1850, was purchased by Harrison Eiteljorg from Richard Rasso in June 1987. It is made of cedar, pigmented in red and black, and is adorned with human hair. It depicts a shaman holding a knife. The top of the knife is carved to resemble a facial expression.

During consultation the Central Council of the Tlingit & Haida Tribes identified the Oyster Catcher Rattle (*Loogán Sheishoo*), Shaman's Staff (*t' Woodzakaayí*), Shaman's Hat, and Shaman Spirit Helper (*yéik*) as cultural items used only by a shaman (*íFD;t'*). Shaman implements would have been interred with a shaman. As it is against Tlingit custom to grant permission to disturb or disinter a shaman's grave the Central Council believes that these four cultural items could have only been collected by removing them from a grave, and therefore, they are unassociated funerary objects. Historic and contemporary scholarly research reiterate that traditionally, Tlingit shamans were buried with their accoutrements such as rattles, staffs, hats, and spirit helpers. As indicated through museum records and consultation with the Central Council,

the cultural affiliation of the four cultural items is Tlingit. According to Tlingit oral tradition, the Tlingit people have owned and occupied southeastern Alaska since time immemorial.

Determinations Made by the Eiteljorg Museum

Officials of the Eiteljorg Museum have determined that:

- Pursuant to 25 U.S.C. 3001(3)(B), the four cultural items described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from a specific burial site of a Native American individual.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the unassociated funerary objects and the Central Council of the Tlingit & Haida Indian Tribes.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to John Vanausdall, President & CEO, Eiteljorg Museum of American Indians and Western Art, 500 W Washington Street, Indianapolis, IN 46204, telephone (317) 275–1313, email *jvanausdall@eiteljorg.com,* by July 3, 2019. After that date, if no additional claimants have come forward, transfer of control of the unassociated funerary objects to the Central Council of the Tlingit & Haida Indian Tribes may proceed.

The Eiteljorg Museum is responsible for notifying the Angoon Community Association; Central Council of the Tlingit & Haida Indian Tribes; Chilkat Indian Village (Klukwan); Chilkoot Indian Association (Haines); Craig Tribal Association (previously listed as the Craig Community Association); Douglas Indian Association; Hoonah Indian Association; Hydaburg Cooperative Association; Ketchikan Indian Corporation; Klawock Cooperative Association; Native Village of Eyak (Cordova); Organized Village of Kake; Organized Village of Saxman; Petersburg Indian Association; Sitka Tribe of Alaska; Skagway Village; Wrangell Cooperative Association; and the Yakutat Tlingit Tribe that this notice has been published.

Dated: May 2, 2019.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2019–11429 Filed 5–31–19; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0027840; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Artesia Historical Museum and Art Center, Artesia, NM

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Artesia Historical Museum and Art Center has completed an inventory of human remains, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the Artesia Historical Museum and Art Center. If no additional requestors come forward, transfer of control of the human remains to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to the Artesia Historical Museum and Art Center at the address in this notice by July 3, 2019.

ADDRESSES: Nancy Dunn, Museum Manager, Artesia Historical Museum and Art Center, 505 West Richardson Avenue, Artesia, NM 88210, telephone (575) 748–2390, email *artesiamuseum@artesianm.gov.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of the Artesia Historical Museum and Art Center, Artesia, NM. The human remains were removed from a cave near Mogollon, Catron County, NM.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Artesia Historical Museum and Art Center. The following tribes with ancestral ties to the Mogollon/Gila Cliff Dwellings area of New Mexico were invited to consult on the human remains: Fort Sill Apache Tribe of Oklahoma; Kewa Pueblo, New Mexico (previously listed as the Pueblo of Santo Domingo); Mescalero Apache Tribe of the Mescalero Reservation, New Mexico; Ohkay Owingeh, New Mexico (previously listed as the Pueblo of San Juan); Pueblo of Acoma, New Mexico; Pueblo of Cochiti, New Mexico; Pueblo of Isleta, New Mexico; Pueblo of Jemez, New Mexico; Pueblo of Laguna, New Mexico; ; Pueblo of Nambe, New Mexico; Pueblo of Picuris, New Mexico; Pueblo of Pojoaque, New Mexico; Pueblo of San Felipe, New Mexico; Pueblo of San Ildefonso, New Mexico; Pueblo of Sandia, New Mexico; Pueblo of Santa Ana, New Mexico; Pueblo of Santa Clara, New Mexico; Pueblo of Taos, New Mexico; Pueblo of Tesuque, New Mexico; Pueblo of Zia, New Mexico; Ysleta del Sur Pueblo (previously listed as the Ysleta Del Sur Pueblo of Texas); and Zuni Tribe of the Zuni Reservation, New Mexico. Hereafter, they are referred to as ''The Invited Tribes.'' To date, none of The Invited Tribes have requested consultation with the Museum.

History and Description of the Remains

In 1968 or 1969, human remains representing, at minimum, one individual were removed from a cave near Mogollon in Catron County, NM. A group of College of Artesia students, led by Dr. Pritchford, collected the human remains from a cave near the Gila Cliff Dwellings National Monument, outside the Federal land boundaries. Dr. Pritchford gave the human remains to fellow College of Artesia faculty member Dr. Stiff, who in turn gave them to Artesia resident Ted Carder. Ted Carder donated the human remains to the Artesia Historical Museum and Art Center in 1971. The 1971 accession record only identifies these human remains as an ''Indian Skull.'' In 2016, a former College of Artesia student provided information that led to the

discovery of the collection history. An osteological examination conducted by the Maxwell Museum of Anthropology in 2016 showed that the human remains, which consist of a partial skull, belonged to an infant aged approximately three months. No known individuals were identified. No associated funerary objects are present.

The Gila Wilderness region of New Mexico, located in the southwest part of the state, is home to the Gila Cliff Dwellings National Monument. This region was originally settled by the Mogollon culture, who abandoned the area for good ca. 1150. Contemporary Pueblo people in the southwest who claim descent from the Mogollon culture have continued the distinctive Mimbres pottery tradition created by the Mimbres Mogollon branch/subgroup of the Mogollon culture.

After the Mogollon culture largely abandoned the Gila Wilderness region, the Apache people lived there, A.D. 1200–1600. Since the skull fragment was in too poor condition for its age to be determined, it may date from either the Mogollon period of occupation (200–1150), or the later Apache occupation (1200–1600).

The human remains have been determined to be ''Native American'' based on their having been collected from a cave burial site in the Gila Wilderness region and their identification as an ''Indian Skull'' in the original accession record.

Determinations Made by the Artesia Historical Museum and Art Center

Officials of the Artesia Historical Museum and Art Center have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and The Invited Tribes.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Nancy Dunn, Museum Manager, Artesia Historical Museum and Art Center, 505 West Richardson Avenue, Artesia, NM 88210, telephone (575) 748–2390, email *artesiamuseum@artesianm.gov,* by July 3, 2019. After that date, if no additional requestors have come forward, transfer of control of the human remains to The Invited Tribes may proceed.

The Artesia Historical Museum and Art Center is responsible for notifying The Invited Tribes that this notice has been published.

Dated: May 2, 2019.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2019–11427 Filed 5–31–19; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0027843; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: University of San Diego, San Diego, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The University of San Diego, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, has determined that the cultural items listed in this notice meet the definition of objects of cultural patrimony. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request to the University of San Diego. If no additional claimants come forward, transfer of control of the cultural items to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to the University of San Diego at the address in this notice by July 3, 2019.

ADDRESSES: Dr. Derrick R. Cartwright, University of San Diego, 5998 Alcala Park, San Diego, CA 92110–8001, telephone (619) 260–7632, email *dcartwright@sandiego.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items under the control of the University of San Diego, San Diego, CA, that meet the definition of objects of cultural patrimony under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural items. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Items

Between the 1950s and the 1990s, 13 cultural items were collected from sites in San Diego County, CA, possibly from Kitchen Creek, Vallecitos, or Hancock Ranch (there are no exact provenience records for these objects). These objects were part of a 1994 donation from the estate of Dorothy Zama May of La Jolla, CA, who was an avid enthusiast of American Indian cultures and traditions of the Southwest United States. The May family traveled throughout the Southwest U.S. and Southern California collecting American Indian art and other objects. The 13 objects of cultural patrimony are one set of bone whistle fragments; two stone pendants; one miniature stone pestle; one stone slab with pictograph; two stone figures; five ceramic pipes; and one stone pipe or sucking tube.

San Diego County is recognized as the aboriginal area of the people of the Kumeyaay Nation and all 13 bands of the Kumeyaay Nation were invited to consult. During consultations with representatives of the Jamul Indian Village of California of the Kumeyaay Nation, tribal members recognized these objects as having been important to their village members, and spoke of how they were used both in the past and present. They related stories of learning about objects similar to these from tribal members. These thirteen objects are likely culturally significant to all of the bands of the Kumeyaay Nation.

Determinations Made by the University of San Diego

Officials of the University of San Diego have determined that:

- Pursuant to 25 U.S.C. 3001(3)(D), the 13 cultural items described above have ongoing historical, traditional, or cultural importance central to the Native American group or culture itself, rather than property owned by an individual.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the objects of cultural patrimony and the Campo Band of Diegueno Mission Indians of the Campo Indian Reservation, California; Capitan

Grande Band of Diegueno Mission Indians of California (Barona Group of Capitan Grande Band of Mission Indians of the Barona Reservation, California; Viejas (Baron Long) Group of Capitan Grande Band of Mission Indians of the Viejas Reservation, California); Ewiiaapaayp Band of Kumeyaay Indians, California; Iipay Nation of Santa Ysabel, California (previously listed as the Santa Ysabel Band of Diegueno Mission Indians of the Santa Ysabel Reservation); Inaja Band of Diegueno Mission Indians of the Inaja and Cosmit Reservation, California; Jamul Indian Village of California; La Posta Band of Diegueno Mission Indians of the La Posta Indian Reservation, California; Manzanita Band of Diegueno Mission Indians of the Manzanita Reservation, California; Mesa Grande Band of Diegueno Mission Indians of the Mesa Grande Reservation, California; San Pasqual Band of Diegueno Mission Indians of California; and the Sycuan Band of the Kumeyaay Nation; hereafter referred to as ''The Tribes.''

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to Dr. Derrick R. Cartwright, University of San Diego, 5998 Alcala Park, San Diego, CA 92110–8001, telephone (619) 260–7632, email *dcartwright@sandiego.edu,* by July 3, 2019. After that date, if no additional claimants have come forward, transfer of control of the objects of cultural patrimony to The Tribes may proceed.

The University of San Diego is responsible for notifying The Tribes that this notice has been published.

Dated: May 2, 2019.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2019–11428 Filed 5–31–19; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–621 and 731–TA–1447 (Preliminary)]

Ceramic Tile From China

Determinations

On the basis of the record [1] developed in the subject investigations, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that there is a reasonable indication that an industry in the United States is materially injured by reason of imports of ceramic tile from China, provided for in subheadings 6907.21.10, 6907.21.20, 6907.21.30, 6907.21.40, 6907.21.90, 6907.22.10, 6907.22.20, 6907.22.30, 6907.22.40, 6907.22.90, 6907.23.10, 6907.23.20, 6907.23.30, 6907.23.40, 6907.23.90, 6907.30.10, 6907.30.20, 6907.30.30, 6907.30.40, 6907.30.90, 6907.40.10, 6907.40.20, 6907.40.30, 6907.40.40, and 6907.40.90 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value (''LTFV'') and to be subsidized by the government of China.[2]

Commencement of Final Phase Investigations

Pursuant to section 207.18 of the Commission's rules, the Commission also gives notice of the commencement of the final phase of its investigations. The Commission will issue a final phase notice of scheduling, which will be published in the **Federal Register** as provided in section 207.21 of the Commission's rules, upon notice from the U.S. Department of Commerce (''Commerce'') of affirmative preliminary determinations in the investigations under sections 703(b) or 733(b) of the Act, or, if the preliminary determinations are negative, upon notice of affirmative final determinations in those investigations under sections 705(a) or 735(a) of the Act. Parties that filed entries of appearance in the preliminary phase of the investigations need not enter a separate appearance for the final phase of the investigations. Industrial users, and, if the merchandise under investigation is sold at the retail level, representative consumer organizations have the right to appear as parties in Commission antidumping and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

Background

On April 10, 2019, the Coalition for Fair Trade in Ceramic Tile filed a petition with the Commission and Commerce, alleging that an industry in the United States is materially injured or threatened with material injury by reason of imports of ceramic tile from China sold in the United States at LTFV and subsidized by the government of China. Accordingly, effective April 10, 2019, the Commission, pursuant to sections 703(a) and 733(a) of the Act (19 U.S.C. 1671b(a) and 1673b(a)), instituted countervailing duty investigation No. 701–TA–621 and antidumping duty investigation No. 731–TA–1447 (Preliminary).

Notice of the institution of the Commission's investigations and of a public conference to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of April 16, 2019 (84 FR 15637). The conference was held in Washington, DC, on May 1, 2019, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission made these determinations pursuant to sections 703(a) and 733(a) of the Act (19 U.S.C. 1671b(a) and 1673b(a)). It completed and filed its determinations in these investigations on May 28, 2019. The views of the Commission are contained in USITC Publication 4898, June 2019, entitled *Ceramic Tile from China: Investigation Nos. 701–TA–621 and 731–TA–1447 (Preliminary).*

By order of the Commission.

Issued: May 29, 2019.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2019–11462 Filed 5–31–19; 8:45 am]

BILLING CODE 7020–02–P

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] 84 FR 20093 and 84 FR 20101 (May 8, 2019).

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–991 (Third Review)]

Silicon Metal From Russia; 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 silicon metal from Russia 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 June 3, 2019. To be assured of consideration, the deadline for responses is July 3, 2019. Comments on the adequacy of responses may be filed with the Commission by August 15, 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 March 26, 2003, the Department of Commerce (''Commerce'') issued an antidumping duty order on imports of silicon metal from Russia (68 FR 14578). Following the first five-year reviews by Commerce and the Commission, effective July 16, 2008, Commerce issued a continuation of the antidumping duty order on imports of silicon metal from Russia (73 FR 40848). Following the second five-year reviews by Commerce and the Commission, effective July 2, 2014, Commerce issued a continuation of the antidumping duty order on imports of silicon metal from Russia (79 FR 37718). The Commission is now conducting a third 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 Russia.

(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, its expedited first five-year review determination, and its full second five-year review determination, the Commission defined the *Domestic Like Product* as all silicon metal, regardless of grade, consistent 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, its expedited first five-year review determination, and its full second five-year review determination, the Commission defined the *Domestic Industry* as all domestic producers of silicon metal, regardless of grade, consistent with Commerce's scope.

(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 July 3, 2019. 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 August 15, 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. 19–5–433, 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 2013.

(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 2018, 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 2018 (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 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 2018 (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 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 2013, 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: May 24, 2019.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2019–11344 Filed 5–31–19; 8:45 am]

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INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–417 and 731–TA–953, 957–959, and 961 (Third Review)]

Carbon and Certain Alloy Steel Wire Rod From Brazil, Indonesia, Mexico, Moldova, and Trinidad and Tobago; 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 countervailing duty order on carbon and certain alloy steel wire rod (''wire rod'') from Brazil and the antidumping duty orders on wire rod from Brazil, Indonesia, Mexico, Moldova, and Trinidad & Tobago 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 June 3, 2019. To be assured of consideration, the deadline for responses is July 3, 2019. Comments on the adequacy of responses may be filed with the Commission by August 15, 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 October 22, 2002, the Department of Commerce (''Commerce'') issued a countervailing duty order on imports of wire rod from Brazil (67 FR 64871). On October 29, 2002, Commerce issued antidumping duty orders on imports of wire rod from Brazil, Indonesia, Mexico, Moldova, and Trinidad & Tobago (67 FR 65944–65947). Following the first five-year reviews by Commerce and the Commission, effective July 30, 2008, Commerce issued a continuation of the countervailing duty order on wire rod from Brazil and the antidumping duty orders on wire rod from Brazil, Indonesia, Mexico, Moldova, and Trinidad & Tobago (73 FR 44218). Following the second five-year reviews by Commerce and the Commission, effective July 3, 2014, Commerce issued a continuation of the countervailing duty order on wire rod from Brazil and the antidumping duty orders on wire rod from Brazil, Indonesia, Mexico, Moldova, and Trinidad & Tobago (79 FR 38008). The Commission is now conducting third 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 Commerce.

(2) The *Subject Countries* in these reviews are Brazil, Indonesia, Mexico, Moldova, and Trinidad & Tobago.

(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 full first and second five-year review determinations, the Commission found a single *Domestic Like Product* encompassing all wire rod, including grade 1080 tire cord and grade 1080 tire bead wire rod that Commerce excluded from the 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 full first and second five-year review determinations, the Commission found a single *Domestic Industry* consisting of all domestic producers of wire rod, including grade 1080 tire cord and grade 1080 tire bead wire rod.

(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 July 3, 2019. 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 August 15, 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://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* 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. 19–5–432, 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: If you are a domestic producer, union/worker group, or trade/business association; import/export *Subject Merchandise* from more than one *Subject Country;* or produce *Subject Merchandise* in more than one *Subject Country,* you may file a single response. If you do so, please ensure that your response to each question includes the information requested for each pertinent *Subject Country.* 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 each *Subject Country* that currently export or have exported *Subject Merchandise* to the United States or other countries after 2013.

(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 2018, 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 any *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2018 (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 each *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 each *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 each *Subject Country.*

(11) If you are a producer, an exporter, or a trade/business association of producers or exporters of the *Subject Merchandise* in any *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2018 (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 each *Subject Country* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm(s) to produce the *Subject Merchandise* in each *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 each *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 each *Subject Country* after 2013, 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 each *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: May 24, 2019.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2019–11343 Filed 5–31–19; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 731–TA–1210–1212 (Review) and 701–TA–454 and 731–TA–1144 (Second Review)]

Welded Stainless Steel Pressure Pipe From China, Malaysia, Thailand, and Vietnam; 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 welded stainless steel pressure pipe from China and the antidumping duty orders on welded stainless steel pressure pipe from Malaysia, Thailand, and Vietnam 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 June 3, 2019. To be assured of consideration, the deadline for responses is July 3, 2019. Comments on the adequacy of responses may be filed with the Commission by August 15, 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 March 17, 2009, the Department of Commerce (''Commerce'') issued an antidumping duty order on imports of welded stainless steel pressure pipe from China (74 FR 11351). On March 19, 2009, Commerce issued a countervailing duty order on imports of welded stainless steel pressure pipe from China (74 FR 11712). Following first five-year reviews by Commerce and the Commission, effective July 23, 2014, Commerce issued a continuation of the antidumping duty order on imports of welded stainless steel pressure pipe from China (79 FR 42760). Effective August 12, 2014, Commerce issued a continuation of the countervailing duty order on imports of welded stainless steel pressure pipe from China (79 FR 47089). On July 21, 2014, Commerce issued antidumping duty orders on imports of welded stainless steel pressure pipe from Malaysia, Thailand, and Vietnam (79 FR 42289). The Commission is now conducting second reviews of the antidumping and countervailing duty orders concerning welded stainless steel pressure pipe from China and first reviews of the antidumping duty orders concerning welded stainless steel pressure pipe from Malaysia, Thailand, and Vietnam 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 Commerce.

(2) The *Subject Countries* in these reviews are China, Malaysia, Thailand, and Vietnam.

(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 concerning China, the Commission defined one *Domestic Like Product* consisting of small-diameter welded stainless steel pressure pipe with an outside diameter not greater than 14 inches, coextensive with Commerce's scope. In its original determinations concerning Malaysia, Thailand, and

Vietnam, the Commission defined one *Domestic Like Product* as welded stainless steel pressure pipe, 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 expedited first five-year review determinations concerning China, the Commission defined the *Domestic Industry* as all U.S. producers of small diameter welded stainless steel pressure pipe with an outside diameter not greater than 14 inches. In its original determinations concerning Malaysia, Thailand, and Vietnam, the Commission defined the *Domestic Industry* as all U.S. producers of welded stainless steel pressure pipe.

(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 July 3, 2019. 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 August 15, 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://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* 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. 19–5–435, 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: If you are a domestic producer, union/worker group, or trade/business association; import/export *Subject Merchandise* from more than one *Subject Country;* or produce *Subject*

Merchandise in more than one *Subject Country,* you may file a single response. If you do so, please ensure that your response to each question includes the information requested for each pertinent *Subject Country.* 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 each *Subject Country* that currently export or have exported *Subject Merchandise* to the United States or other countries after 2013.

(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 2018, 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 any *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2018 (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 each *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 each *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 each *Subject Country.*

(11) If you are a producer, an exporter, or a trade/business association of producers or exporters of the *Subject Merchandise* in any *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2018 (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 each *Subject Country* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm(s) to produce the *Subject Merchandise* in each *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 each *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 each *Subject Country* after 2013, 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 each *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: May 24, 2019.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2019–11345 Filed 5–31–19; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–499–500 and 731–TA–1215–1216, 1221–1223 (Review)]

Oil Country Tubular Goods From India, Korea, Turkey, Ukraine, and Vietnam; 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 countervailing duty orders on oil country tubular goods from India and Turkey, revocation of the antidumping duty orders on oil country tubular goods from India, Korea, Turkey, and Vietnam, and termination of the suspended investigation on oil country tubular goods from Ukraine 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 June 3, 2019. To be assured of consideration, the deadline for responses is July 3, 2019. Comments on the adequacy of responses may be filed with the Commission by August 15, 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 10, 2014, the Department of Commerce (''Commerce'') suspended an antidumping duty investigation on imports of oil country tubular goods from Ukraine (79 FR 41959, July 18, 2014). On September 10, 2014, Commerce issued countervailing duty orders on imports of oil country tubular goods from India and Turkey (79 FR 53688) and antidumping duty orders on imports of oil country tubular goods from India, Korea, Turkey, and Vietnam (79 FR 53691). The Commission is conducting reviews pursuant to section 751(c) of the Act, as amended (19 U.S.C. 1675(c)), to determine whether revocation of the orders on imports of oil country tubular goods from India, Korea, Turkey, and Vietnam and whether termination of the suspended investigation concerning imports of oil country tubular goods from Ukraine 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 Commerce.

(2) The *Subject Countries* in these reviews are India, Korea, Turkey, Ukraine, and Vietnam.

(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, the Commission defined the *Domestic Like Product* as all oil country tubular goods, 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, the Commission defined the *Domestic Industry* to include all U.S. producers of oil country tubular goods, including both mills that produce oil country tubular goods and processors that engage in heat treatment.

(5) The *Order Dates* are the dates that the antidumping and countervailing duty orders under review became effective and the date the investigation concerning Ukraine was suspended. In these reviews, the *Order Date* concerning the countervailing duty orders on oil country tubular goods from India and Turkey and the antidumping duty orders on oil country tubular goods from India, Korea, Turkey, and Vietnam is September 10, 2014. The *Order Date* concerning the suspended investigation on oil country tubular goods from Ukraine is July 10, 2014.

(6) 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 July 3, 2019. 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 August 15, 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://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* 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. 19–5–434, 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: If you are a domestic producer, union/worker group, or trade/business association; import/export *Subject Merchandise* from more than one *Subject Country;* or produce *Subject Merchandise* in more than one *Subject Country,* you may file a single response. If you do so, please ensure that your response to each question includes the information requested for each pertinent *Subject Country.* 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 Merchandise*, 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 and termination of the suspended investigation 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 each *Subject Country* that currently export or have exported *Subject Merchandise* to the United States or other countries since the *Order Date*.

(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 2018, 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 any *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2018 (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 each *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 each *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 each *Subject Country*.

(11) If you are a producer, an exporter, or a trade/business association of producers or exporters of the *Subject Merchandise* in any *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2018 (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 each *Subject Country* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm(s) to produce the *Subject Merchandise* in each *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 each *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 each *Subject Country* since the *Order Date,* 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 each *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: May 24, 2019.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2019–11342 Filed 5–31–19; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Antitrust Division

United States v. Gray Television, Inc., et al.; Response to Public Comment

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h), that one comment was received concerning the proposed Final Judgment in this case, and that comment together with the Response of Plaintiff United States to Public Comment on the Proposed Final Judgment have been filed with the United States District Court for the District of Columbia in *United States of America* v. *Gray Television, Inc., et al.,* Civil Action No. 1:18–cv–02951–CRC. Copies of the comment and the United States' response are available for inspection on the Antitrust Division's website at *https://www.justice.gov/atr* and at the Office of the Clerk of the United States District Court for the District of Columbia. Copies of these materials may be obtained from the Antitrust Division upon request and payment of the copying fee set by Department of Justice regulations.

Patricia A. Brink,

Director of Civil Enforcement.

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

United States of America, Plaintiff, v. *Gray Television, Inc.,* and *Raycom Media, Inc.,* Defendants.

Case No. 1:18–cv–02951–CRC

RESPONSE OF PLAINTIFF UNITED STATES TO PUBLIC COMMENT ON THE PROPOSED FINAL JUDGMENT

As required by the Antitrust Procedures and Penalties Act (the ''APPA'' or ''Tunney Act''), 15 U.S.C. § 16(b)–(h), the United States hereby responds to the one public comment received by the United States about the proposed Final Judgment in this case. After careful consideration of the submitted comment, the United States continues to believe that the proposed remedy, as described in the proposed Final Judgment, will address the harm alleged in the Complaint and is therefore in the public interest. The United States will move the Court for entry of the proposed Final Judgment after the public comment and this response have been published in the **Federal Register** pursuant to 15 U.S.C. § 16(d).

I. PROCEDURAL HISTORY

On June 23, 2018, Gray Television, Inc. (''Gray'') and Raycom Media, Inc. (''Raycom'') entered into an Agreement and Plan of Merger pursuant to which Gray would acquire Raycom for approximately $3.6 billion. On December 14, 2018, the United States filed a civil antitrust Complaint seeking to enjoin Gray and Raycom (collectively, ''Defendants'') from carrying out the merger. The Complaint alleges that the merger would substantially lessen competition in the markets for the licensing of ''Big 4'' television retransmission consent and the sale of broadcast television spot advertising in each of nine Designated Market Areas (''DMAs'') in which Gray and Raycom each owned an affiliate of a ''Big 4'' television network (i.e., an NBC, CBS, ABC, or FOX affiliate). These nine DMAs (the ''Overlap DMAs'') are: (i) Waco-Temple-Bryan, Texas; (ii) Tallahassee, Florida-Thomasville, Georgia; (iii) Toledo, Ohio; (iv) Odessa-Midland, Texas; (v) Knoxville, Tennessee; (vi) Augusta, Georgia; (vii) Panama City, Florida; (viii) Dothan, Alabama; and (ix) Albany, Georgia.

Simultaneously with the filing of the Complaint, the United States filed a proposed Final Judgment and a Hold Separate Stipulation and Order (''Hold Separate'') signed by Plaintiff and Defendants consenting to entry of the proposed Final Judgment after compliance with the requirements of the Tunney Act, 15 U.S.C. § 16(b)–(h). Pursuant to those requirements, the United States filed a Competitive Impact Statement (''CIS'') on December 14, 2018, describing the transaction and the proposed Final Judgment. 15 U.S.C. § 16(b). The United States published the Complaint, proposed Final Judgment, and CIS in the **Federal Register** on February 1, 2019, *see* 84 Fed. Reg. 1,216 (2019), and caused summaries of the proposed Final Judgment and CIS, together with directions for the submission of written comments related to the proposed Final Judgment, to be published in *The Washington Post* for seven days, from February 4, 2019, through February 10, 2019,[1] *see* 15 U.S.C. § 16(c). The 60-day public comment period required by the Tunney Act, 15 U.S.C. § 16(b)–(d), ended on April 5, 2019. The United States received one comment, which is described below in Section IV, concerning the allegations in the Complaint (Exhibit 1).

II. THE COMPLAINT, THE HOLD SEPARATE, AND THE PROPOSED FINAL JUDGMENT

The Complaint alleged that Gray's acquisition of Raycom would substantially lessen competition in the licensing of Big 4 television retransmission consent and in the sale of broadcast television spot advertising in the Overlap DMAs. The proposed Final Judgment remedies this concern by requiring the Defendants to divest the Big 4 stations owned by either Gray or Raycom in each Overlap DMA. Without the proposed remedy, Gray's acquisition of Raycom would have resulted in the combined company owning an additional Big 4 station in each Overlap DMA.

Big 4 stations usually are the stations in each DMA ranked highest in terms of audience share and ratings, largely because of unique offerings such as local news, sports, and highly ranked primetime programs. Due to these features, multichannel video programming distributors (''MVPDs''), such as cable and satellite television providers, regard Big 4 broadcast stations as highly desirable for inclusion in the packages they offer subscribers. Viewers typically consider Big 4 stations to be close substitutes for one another. If an MVPD suffers a blackout of a Big 4 station in a given DMA, many of the MVPD's subscribers are likely to turn to other Big 4 stations in the DMA to watch similar content. The combination of Gray's and Raycom's Big 4 stations would have increased the combined company's bargaining leverage against MVPDs in the Overlap DMAs, likely leading to increased ''retransmission consent'' fees, which generally are passed on to MVPD subscribers.

In addition to licensing retransmission consent, broadcast television stations sell advertising ''spots'' during breaks in their programming. An advertiser purchases spots from a broadcast station in order to reach viewers within the DMA in which the broadcast station is located. From an advertiser's perspective, broadcast television spot advertising possesses a unique combination of attributes that sets it apart from other kinds of advertising. Gray and Raycom compete to sell broadcast television advertising in each of the Overlap DMAs. Without the divestiture of a Big 4 station in each Overlap DMA,

[1] Though not expressly required to do so by the Tunney Act, the United States also caused these summaries of the proposed Final Judgment and CIS, and directions for submission of written comments, to be published for seven days over a period of two weeks in 11 other newspapers that are widely read in the Overlap DMAs: *The Albany Herald*, *The Augusta Chronicle*, the *Dothan Eagle*, the *Waco Tribune-Herald*, *The Knoxville News-Sentinel*, the *Midland Reporter-Telegram*, *The Odessa American*, *The News Herald* (published in Panama City, Florida), the *Tallahassee Democrat*, *The Blade* (published in Toledo, Ohio), and *The Valdosta Daily Times*. The last date of publication of the materials in any of these newspapers was February 19, 2019.

advertisers would have fewer broadcast television alternatives, likely resulting in increased prices for broadcast television spot advertising.

On August 22, 2018, the Defendants provided the United States with executed asset purchase agreements under which the Defendants proposed to divest the following Big 4 stations:

(a) Raycom-owned KXXV and KRHD-CD, the ABC affiliates in the Waco-Temple-Bryan, Texas, DMA, and WTXL-TV, the ABC affiliate in the Tallahassee, Florida-Thomasville, Georgia, DMA to the E.W. Scripps Company or its subsidiaries (collectively ''Scripps'');

(b) Raycom-owned WTOL, the CBS affiliate in the Toledo, Ohio, DMA, and KWES-TV, the NBC affiliate in the Odessa-Midland, Texas, DMA to TEGNA Inc. or its subsidiaries (collectively ''TEGNA'');

(c) Raycom-owned WTNZ, the FOX affiliate in the Knoxville, Tennessee, DMA, WFXG, the FOX affiliate in the Augusta, Georgia, DMA, WPGX, the FOX affiliate in the Panama City, Florida, DMA, and WDFX-TV, the FOX affiliate in the Dothan, Alabama, DMA to Greensboro TV, LLC, a company controlled by Jim Lockwood (''Lockwood''); and

(d) Gray-owned WSWG, the CBS affiliate in the Albany, Georgia, DMA to Marquee Broadcasting Georgia, Inc. (''Marquee'').

The United States investigated the sufficiency of the proposed divestitures for addressing competitive concerns with the proposed merger by reviewing documents and information from the proposed divestiture buyers and interviewing their executives. After this review, the United States concluded that the divestiture of the assets to each proposed purchaser would not cause competitive harm; each purchaser has an incentive to use the divestiture assets to compete in the relevant markets; and each purchaser has sufficient acumen, experience, and financial capability to compete effectively in the market over the long term. Each of the approved buyers has financial capability and experience running multiple broadcast television stations, including Big 4 affiliates. Moreover, each buyer has the experience and sophistication necessary to manage the assets its purchasing, plans to use the assets to compete in the markets in which they are located, and has no other entanglements suggesting the divestitures would result in any competitive harm. Accordingly, the Division concluded that the divestiture of broadcast stations and related assets to Scripps, TEGNA, Lockwood, and Marquee, resolved the competitive concerns set forth in the Complaint. On January 2, 2019 Gray consummated its acquisition of Raycom.

The Hold Separate and the proposed Final Judgment were filed with the court on December 14, 2018. Under the proposed Final Judgment, the Defendants are required to divest the television stations set forth in the proposed asset purchase agreements and all assets necessary for their operation as viable, ongoing commercial broadcast television stations.[2] The proposed Final Judgment requires that these assets be divested to one or more acquirers acceptable to the United States, in its sole discretion. On December 31, 2018, and January 2, 2019, Gray sold the divestiture assets set forth in the proposed Final Judgment to Scripps, TEGNA, Lockwood, and Marquee, as approved by the United States. On January 2, 2019, Gray consummated its acquisition of Raycom.

Under the Hold Separate, the United States and the Defendants have stipulated that the proposed Final Judgment may be entered after compliance with the APPA. Entry of the proposed Final Judgment would terminate this action, except that the court would retain jurisdiction to construe, modify, or enforce the provisions of the proposed Final Judgment and to punish violations thereof.

III. STANDARD OF JUDICIAL REVIEW

The Clayton Act, as amended by the APPA, requires that proposed consent judgments in antitrust cases brought by the United States be subject to a public comment period of at least 60 days, after which the court shall determine whether entry of the proposed Final Judgment ''is in the public interest.'' 15 U.S.C. § 16(e)(1). In making that determination, the court, in accordance with the statute as amended in 2004, is required to consider:

(A) the competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration of relief sought, anticipated effects of alternative remedies actually considered, whether its terms are ambiguous, and any other competitive considerations bearing upon the adequacy of such judgment that the court deems necessary to a determination of whether the consent judgment is in the public interest; and

(B) the impact of entry of such judgment upon competition in the relevant market or markets, upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. § 16(e)(1)(A) & (B). In considering these statutory factors, the court's inquiry is necessarily a limited one as the government is entitled to ''broad discretion to settle with the defendant within the reaches of the public interest.'' *United States v. Microsoft Corp.*, 56 F.3d 1448, 1461 (D.C. Cir. 1995); *see generally United States v. SBC Commc'ns, Inc.*, 489 F. Supp. 2d 1 (D.D.C. 2007) (assessing public-interest standard under the Tunney Act); *United States v. U.S. Airways Group, Inc.*, 38 F. Supp. 3d 69, 75 (D.D.C. 2014) (explaining that the ''court's inquiry is limited'' in Tunney Act settlements); *United States v. InBev N.V./S.A.*, No. 08-1965 (JR), 2009 U.S. Dist. LEXIS 84787, at *3 (D.D.C. Aug. 11, 2009) (noting that the court's review of a consent judgment is limited and only inquires ''into whether the government's determination that the proposed remedies will cure the antitrust violations alleged in the complaint was reasonable, and whether the mechanisms to enforce the final judgment are clear and manageable'').

As the U.S. Court of Appeals for the District of Columbia Circuit has held, under the APPA a court considers, among other things, the relationship between the remedy secured and the specific allegations in the government's complaint, whether the decree is sufficiently clear, whether its enforcement mechanisms are sufficient, and whether the decree may positively harm third parties. *See Microsoft*, 56 F. 3d at 1458-62. With respect to the adequacy of the relief secured by the decree, a court may not ''engage in an unrestricted evaluation of what relief would best serve the public.'' *United States v. BNS, Inc.*, 858 F.2d 456, 462 (9th Cir. 1988) (quoting *United States v. Bechtel Corp.*, 648 F.2d 660, 666 (9th Cir. 1981)); *see also Microsoft*, 56 F.3d at 1460–62; *United States v. Alcoa, Inc.*, 152 F. Supp. 2d 37, 40 (D.D.C. 2001); *InBev*, 2009 U.S. Dist. LEXIS 84787, at *3. Instead:

[t]he balancing of competing social and political interests affected by a proposed antitrust consent decree must be left, in

[2] The proposed Final Judgment contemplates that Gray would not be required to divest certain excluded assets, namely, the Telemundo and CW affiliations and programming streams in the Odessa-Midland, Texas, DMA; the Telemundo affiliation and programming stream in the Waco-Temple-Bryan, Texas, DMA; and the CW affiliation and programming stream in the Albany, Georgia, DMA. The United States has concluded that Gray's retention of these programming streams would not have a material effect on the adequacy of the proposed remedy.

the first instance, to the discretion of the Attorney General. The court's role in protecting the public interest is one of insuring that the government has not breached its duty to the public in consenting to the decree. The court is required to determine not whether a particular decree is the one that will best serve society, but whether the settlement is ''*within the reaches of the public interest*.'' More elaborate requirements might undermine the effectiveness of antitrust enforcement by consent decree.

Bechtel, 648 F.2d at 666 (emphasis added) (citations omitted).[3]

In determining whether a proposed settlement is in the public interest, a district court ''must accord deference to the government's predictions about the efficacy of its remedies, and may not require that the remedies perfectly match the alleged violations.'' *SBC Commc'ns*, 489 F. Supp. 2d at 17; *see also U.S. Airways*, 38 F. Supp. 3d at 74-75 (noting that a court should not reject the proposed remedies because it believes others are preferable and that room must be made for the government to grant concessions in the negotiation process for settlements); *Microsoft*, 56 F.3d at 1461 (noting the need for courts to be ''deferential to the government's predictions as to the effect of the proposed remedies''); *United States v. Archer- Daniels-Midland Co.*, 272 F. Supp. 2d 1, 6 (D.D.C. 2003) (noting that the court should grant ''due respect to the government's prediction as to the effect of proposed remedies, its perception of the market structure, and its views of the nature of the case''). The ultimate question is whether ''the remedies [obtained in the decree are] so inconsonant with the allegations charged as to fall outside of the 'reaches of the public interest.''' *Microsoft*, 56 F.3d at 1461 (*quoting United States v. Western Elec. Co.*, 900 F.2d 283, 309 (D.C. Cir. 1990)). To meet this standard, the United States ''need only provide a factual basis for concluding that the settlements are reasonably adequate remedies for the alleged harms.'' *SBC Commc'ns*, 489 F. Supp. 2d at 17.

Moreover, the court's role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its complaint, and does not authorize the court to ''construct [its] own hypothetical case and then evaluate the decree against that case.'' *Microsoft*, 56 F.3d at 1459; *see also U.S. Airways*, 38 F. Supp. 3d at 75 (noting that the court must simply determine whether there is a factual foundation for the government's decisions such that its conclusions regarding the proposed settlements are reasonable); *InBev*, 2009 U.S. Dist. LEXIS 84787, at *20 (''the 'public interest' is not to be measured by comparing the violations alleged in the complaint against those the court believes could have, or even should have, been alleged''). Because the ''court's authority to review the decree depends entirely on the government's exercising its prosecutorial discretion by bringing a case in the first place,'' it follows that ''the court is only authorized to review the decree itself,'' and not to ''effectively redraft the complaint'' to inquire into other matters that the United States did not pursue. *Microsoft*, 56 F.3d at 1459–60. As a court in this district confirmed in *SBC Communications*, courts ''cannot look beyond the complaint in making the public interest determination unless the complaint is drafted so narrowly as to make a mockery of judicial power.'' *SBC Commc'ns*, 489 F. Supp. 2d at 15.

In its 2004 amendments to the APPA,[4] Congress made clear its intent to preserve the practical benefits of utilizing consent decrees in antitrust enforcement, adding the unambiguous instruction that ''[n]othing in this section shall be construed to require the court to conduct an evidentiary hearing or to require the court to permit anyone to intervene.'' 15 U.S.C. § 16(e)(2); *see also U.S. Airways*, 38 F. Supp. 3d at 76 (indicating that a court is not required to hold an evidentiary hearing or to permit intervenors as part of its review under the Tunney Act). This language explicitly wrote into the statute what Congress intended when it first enacted the Tunney Act in 1974. As Senator Tunney explained: ''[t]he court is nowhere compelled to go to trial or to engage in extended proceedings which might have the effect of vitiating the benefits of prompt and less costly settlement through the consent decree process.'' 119 Cong. Rec. 24,598 (1973) (statement of Sen. Tunney). Rather, the procedure for the public-interest determination is left to the discretion of the court, with the recognition that the court's ''scope of review remains sharply proscribed by precedent and the nature of Tunney Act proceedings.'' *SBC Commc'ns*, 489 F. Supp. 2d at 11. A court can make its public-interest determination based on the competitive impact statement and response to public comments alone. *U.S. Airways*, 38 F. Supp. 3d at 76; *see also United States v. Enova Corp.*, 107 F. Supp. 2d 10, 17 (D.D.C. 2000) (noting that the ''Tunney Act expressly allows the court to make its public interest determination on the basis of the competitive impact statement and response to comments alone''); S. Rep. No. 93-298 93d Cong., 1st Sess., at 6 (1973) (''Where the public interest can be meaningfully evaluated simply on the basis of briefs and oral arguments, that is the approach that should be utilized.'').

IV. SUMMARY OF PUBLIC COMMENT AND THE UNITED STATES' RESPONSE

During the public comment period, the United States received only one comment concerning the proposed Final Judgment in this litigation. That comment, attached as Exhibit 1, is a letter from a self-described ''television viewer'' in Dothan, Alabama, one of the Overlap DMAs. The comment takes issue with Gray acquiring additional Big 4 stations in Dothan. As required by the APPA, the comment, and the United States' response, will be published in the **Federal Register**.

The United States believes that nothing in this comment warrants a change to the proposed Final Judgment or supports an inference that the proposed Final Judgment is not in the public interest. While the proposed merger would, absent the remedy, have put more Big 4 affiliate stations under Gray's control, the proposed Final Judgment avoids this result. In Dothan, Alabama, where Gray owns the CBS and NBC affiliates, the merger would have resulted in Gray also owning the FOX affiliate, WDFX-TV. As noted above, however, WDFX-TV was one of the stations sold to Lockwood on January 2, 2019. Therefore, consistent with the concerns expressed by the commenter, the proposed Final Judgment prevents Gray from increasing its control over television affiliates in Dotham.

CONCLUSION

After reviewing the public comment, the United States continues to believe that the proposed Final Judgment, as drafted, provides an effective and appropriate remedy for the antitrust violations alleged in the Complaint, and is therefore in the public interest. The

[3] *See also BNS*, 858 F.2d at 464 (holding that the court's ''ultimate authority under the [APPA] is limited to approving or disapproving the consent decree''); *United States v. Gillette Co.*, 406 F. Supp. 713, 716 (D. Mass. 1975) (noting that, in this way, the court is constrained to ''look at the overall picture not hypercritically, nor with a microscope, but with an artist's reducing glass'').

[4] The 2004 amendments substituted ''shall'' for ''may'' in directing relevant factors for a court to consider and amended the list of factors to focus on competitive considerations and to address potentially ambiguous judgment terms. *Compare* 15 U.S.C. § 16(e) (2004), *with* 15 U.S.C. § 16(e)(1) (2006); *see also SBC Commc'ns*, 489 F. Supp. 2d at 11 (concluding that the 2004 amendments ''effected minimal changes'' to Tunney Act review).

United States will move that this Court enter the proposed Final Judgment after the comment and this response are published in the **Federal Register**.

Dated: May 20, 2019

Respectfully submitted,

Gregg I. Malawer,
United States Department of Justice,
Antitrust Division, 450 Fifth Street NW, Suite 4000, Washington, DC 20530, Tel: 202-616-5943, gregg.malawer@usdoj.gov.
Counsel for the United States.

BILLING CODE 4410–11–P

EXHIBIT 1

2-8-2019

Sha'nah S. Martin
[redacted]

Owen Kendler, Chief
Media, Entertainment and Professional Ser. Sect.
Antitrust Division
Dep. of Justice
450 Fifth St. N.W.
Suite 4000
Washington, DC 20530

Dear Mr. Kendler:

I read your name in the legal notices of the local paper, The Dothan Eagle. While my remarks may not reflect on this case, Unites States of America V. Gray Television, Inc., et al, Civil Action No. 1:18-CV-2951-CRC, these thoughts will reflect how the actions of Gray Television and companies like Gray impact people like me, the TV viewer. I am bewildered at how my television viewing is limited because someone deemed it okay to have multiple networks (ABC, NBC, CBS) to be controlled by one company so there is not a bit of local coverage from Panama City or Montgomery as we once had. I realize it is all about money and the advertising dollars, but as a television viewer, the concept is a railroading of my preferences.

If the actions in this suit puts more local networks in Gray Television, Inc., then I am against it.

Sincerely,

Sha'nah S. Martin

P.S. I would appreciate it if you would send me one of business cards. It would be interesting to see all that information on one side of a card.

[FR Doc. 2019–11489 Filed 5–31–19; 8:45 am]

BILLING CODE 4410–11–C

DEPARTMENT OF JUSTICE

[OMB Number 1103–0100]

Agency Information Collection Activities: Extension Requested; Comments Requested; Monitoring Information Collections

ACTION: 30 day notice.

SUMMARY: The Department of Justice (DOJ) Office of Community Oriented Policing Services (COPS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: The purpose of this notice is to allow for 30 days for public comment July 3, 2019.

FOR FURTHER INFORMATION CONTACT: If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Lashon M. Hilliard, Department of Justice Office of Community Oriented Policing Services, 145 N Street NE, Washington, DC 20530.

Written comments and/or suggestions can also be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20530 or sent to *OIRA_submissions@omb.eop.gov*.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—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.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Monitoring Information Collections.

(3) *Agency form number: 1103–0100* U.S. Department of Justice Office of Community Oriented Policing Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: COPS Office hiring grantees that are selected for in-depth monitoring of their grant implementation and equipment grantees that report using COPS funds to implement a criminal intelligence system will be required to respond. The Monitoring Information Collections include two types of information collections: The Monitoring Request for Documentation and the 28 CFR part 23 Monitoring Kit.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that 150 respondents annually will complete the Monitoring Request for Documentation at 3 hours per respondent.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 450 total annual burden hours associated with this collection.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, Washington, DC 20530.

Dated: May 28, 2019.

Melody Braswell,

Department Clearance Officer, PRA, U.S. Department of Justice.

[FR Doc. 2019–11431 Filed 5–31–19; 8:45 am]

BILLING CODE 4410–AT–P

DEPARTMENT OF LABOR

Office of the Secretary

All Items Consumer Price Index for All Urban Consumers; United States City Average

Pursuant to Section 112 of the 1976 amendments to the Federal Election Campaign Act, 52 U.S.C. 30116(c), the Secretary of Labor has certified to the Chairman of the Federal Election Commission and publishes this notice in the **Federal Register** that the United States City Average All Items Consumer Price Index for All Urban Consumers (1967 = 100) increased 409.3 percent from its 1974 annual average of 147.7 to its 2018 annual average of 752.205 and that it increased 41.8 percent from its 2001 annual average of 530.4 to its 2018 annual average of 752.205. Using 1974 as a base (1974 = 100), I certify that the United States City Average All Items Consumer Price Index for All Urban Consumers thus increased 409.3 percent from its 1974 annual average of 100 to its 2018 annual average of 509.279. Using 2001 as a base (2001 = 100), I certify that the United States City Average All Items Consumer Price Index for All Urban Consumers increased 41.8 percent from its 2001 annual average of 100 to its 2018 annual average of 141.818. Using 2006 as a base (2006 = 100), I certify that the Consumer Price Index increased 24.6 percent from its 2006 annual average of 100 to its 2018 annual average of 124.558.

Signed at Washington, DC, on May 21, 2019.

R. Alexander Acosta,

Secretary of Labor.

[FR Doc. 2019–11513 Filed 5–31–19; 8:45 am]

BILLING CODE 4510–24–P

DEPARTMENT OF LABOR

Office of the Secretary

All Items Consumer Price Index for All Urban Consumers; United States City Average

Pursuant to Section 33105(c) of Title 49, United States Code, and the delegation of the Secretary of Transportation's responsibilities under that Act to the Administrator of the Federal Highway Administration (49 CFR, Section 501.2 (a)(9)), the Secretary of Labor has certified to the Administrator and published this notice in the **Federal Register** that the United States City Average All Items Consumer Price Index for All Urban Consumers (1967 = 100) increased 141.8 percent from its 1984 annual average of 311.1 to its 2018 annual average of 752.205.

Signed at Washington, DC, on May 21, 2019.

R. Alexander Acosta,

Secretary of Labor.

[FR Doc. 2019–11514 Filed 5–31–19; 8:45 am]

BILLING CODE 4510–24–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–19–0006; NARA–2019–026]

Records Schedules; Availability and Request for Comments

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of availability of proposed records schedules; request for comments.

SUMMARY: The National Archives and Records Administration (NARA) publishes notice of certain Federal agency requests for records disposition authority (records schedules). We publish notice in the **Federal Register** and on *regulations.gov* for records schedules in which agencies propose to dispose of records they no longer need to conduct agency business. We invite public comments on such records schedules.

DATES: NARA must receive comments by July 18, 2019.

ADDRESSES: You may submit comments by either of the following methods. You must cite the control number, which appears on the records schedule in parentheses after the name of the agency that submitted the schedule.

- *Federal eRulemaking Portal: http://www.regulations.gov.*
- *Mail:* Records Appraisal and Agency Assistance (ACR); National Archives and Records Administration; 8601 Adelphi Road; College Park, MD 20740–6001.

FOR FURTHER INFORMATION CONTACT: Records Management Operations by email at *request.schedule@nara.gov,* by mail at the address above, or by phone at 301–837–1799.

SUPPLEMENTARY INFORMATION:

Public Comment Procedures

We are publishing notice of records schedules in which agencies propose to dispose of records they no longer need to conduct agency business. We invite public comments on these records schedules, as required by 44 U.S.C. 3303a(a), and list the schedules at the end of this notice by agency and subdivision requesting disposition authority.

In addition, this notice lists the organizational unit(s) accumulating the records or states that the schedule has agency-wide applicability. It also provides the control number assigned to each schedule, which you will need if you submit comments on that schedule.

We have uploaded the records schedules and accompanying appraisal memoranda to the regulations.gov docket for this notice as ''other'' documents. Each records schedule contains a full description of the records at the file unit level as well as their proposed disposition. The appraisal memorandum for the schedule includes information about the records.

We will post comments, including any personal information and attachments, to the public docket unchanged. Because comments are public, you are responsible for ensuring that you do not include any confidential or other information that you or a third party may not wish to be publicly posted. If you want to submit a comment with confidential information or cannot otherwise use the regulations.gov portal, you may contact *request.schedule@nara.gov* for instructions on submitting your comment.

We will consider all comments submitted by the posted deadline and consult as needed with the Federal agency seeking the disposition authority. After considering comments, we will post on regulations.gov a ''Consolidated Reply'' summarizing the comments, responding to them, and noting any changes we have made to the proposed records schedule. We will then send the schedule for final approval by the Archivist of the United States. You may elect at regulations.gov to receive updates on the docket, including an alert when we post the Consolidated Reply, whether or not you submit a comment. You may request additional information about the disposition process through the contact information listed above.

We will post schedules on our website in the Records Control Schedule (RCS) Repository, at *https://www.archives.gov/records-mgmt/rcs,* after the Archivist approves them. The RCS contains all schedules approved since 1973.

Background

Each year, Federal agencies create billions of records. To control this accumulation, agency records managers prepare schedules proposing retention periods for records and submit these schedules for NARA's approval. Once approved by NARA, records schedules provide mandatory instructions on what happens to records when no longer needed for current Government business. The records schedules authorize agencies to preserve records of continuing value in the National Archives or to destroy, after a specified period, records lacking continuing administrative, legal, research, or other value. Some schedules are comprehensive and cover all the records of an agency or one of its major subdivisions. Most schedules, however, cover records of only one office or program or a few series of records. Many of these update previously approved schedules, and some include records proposed as permanent.

Agencies may not destroy Federal records without the approval of the Archivist of the United States. The Archivist grants this approval only after thorough consideration of the records' administrative use by the agency of origin, the rights of the Government and of private people directly affected by the Government's activities, and whether or not the records have historical or other value. Public review and comment on these records schedules is part of the Archivist's consideration process.

Schedules Pending

1. Department of the Air Force, Agency-wide, Chaplain Activities (DAA–AFU–2017–0010).
2. Department of the Air Force, Agency-wide, Nursing (DAA–AFU–2018–0002).
3. Department of the Army, Agency-wide, Non-Army Managed Item Supply Discrepancy Report System Master Files (DAA–AU–2016–0008).
4. Department of Defense, Office of the Secretary of Defense, Defense Health Agency Spectacle Request and Transmission System Master Files (DAA–0330–2017–0007).
5. Department of Defense, Office of the Secretary of Defense, Surgical Scheduling System Master Files (DAA–0330–2017–0008).
6. Department of Homeland Security, Transportation Security Administration, Law Enforcement Officers Safety Act (LEOSA) Program (DAA–0560–2019–0005).
7. Department of Homeland Security, United States Citizenship and Immigration Services, Quality Assurance Database (DAA–0566–2019–0017).
8. Department of State, Office of the Secretary of State, The Sounding Board (DAA–0059–2018–0002).
9. Department of Transportation, Federal Highway Administration, Highway Safety Information System (DAA–0406–2019–0003).
10. Federal Mine Safety and Health Review Commission, Agency-wide, Office of Administrative Law Judges (DAA–0470–2019–0002).
11. National Archives and Records Administration, Agency-wide, Audiovisual Records (DAA–0064–2018–0006).
12. Peace Corps, Office of 3rd Goal and Returned Volunteer Services,

Volunteer Description of Services (DAA–0490–2018–0004).

13. Railroad Retirement Board, Office of Administration, Records of the Office of Equal Opportunity (DAA–0184–2018–0010).

Laurence Brewer,

Chief Records Officer for the U.S. Government.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85948; File No. SR–CboeBZX–2019–044]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing of a Proposed Rule Change To Allow the JPMorgan Core Plus Bond ETF of the J.P. Morgan Exchange-Traded Fund Trust To Hold Certain Instruments in a Manner That May Not Comply With Rule 14.11(i), Managed Fund Shares

May 28, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 15, 2019, Cboe BZX Exchange, Inc. (''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes a rule change to allow the JPMorgan Core Plus Bond ETF (the ''Fund'') of the J.P. Morgan Exchange-Traded Fund Trust (the ''Trust'' or the ''Issuer'') to hold certain instruments in a manner that may not comply with Rule 14.11(i) (''Managed Fund Shares''). The shares of the Fund are referred to herein as the ''Shares.''

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/bzx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Shares began trading on the Exchange on January 30, 2019, pursuant to the to the generic listing standards applicable to Managed Fund Shares under Rule 14.11(i)[3] (the ''Generic Listing Standards'') and are currently listed on the Exchange pursuant to a rule filing that was approved by the Commission on April 22, 2019 granting certain exceptions to the Generic Listing Standards.[4] The Original Approval Order allows the Fund to hold instruments in a manner that may not comply with Rule 14.11(i)(4)(C)(ii)(d),[5] Rule 14.11(i)(4)(C)(iv)(b),[6] and/or Rule 14.11(i)(4)(C)(i).[7] Otherwise, the Fund complies with all other listing requirements on an initial and continued listing basis under Rule 14.11(i).

While the Fund currently meets all of the continued listing requirements applicable under the Original Approval Order, the Adviser would like to increase the flexibility of the Fund's holdings in a way that might not meet such requirements. As such, the Exchange submits this proposal in order to allow the Shares to continue listing and trading on the Exchange while holding certain instruments in a manner that, in addition to the exceptions to the Generic Listing Standards provided under the Original Approval Order, also may not comply with three [sic] of the quantitative requirements under the Generic Listing Standards. Specifically, the Exchange submits this proposal in order to allow the Fund to hold instruments in a manner that may not comply with Rule 14.11(i)(4)(C)(ii)(a)[8]

[3] The Commission approved Rule 14.11(i) in Securities Exchange Act Release No. 65225 (August 30, 2011), 76 FR 55148 (September 6, 2011) (SR–BATS–2011–018).

[4] *See* Securities Exchange Act Release No. 85701 (April 22, 2019) (SR–CboeBZX–2019–016) (the ''Original Approval Order'').

[5] Rule 14.11(i)(4)(C)(ii)(d) provides that ''component securities that in aggregate account for at least 90% of the fixed income weight of the portfolio must be either: (a) From issuers that are required to file reports pursuant to Sections 13 and 15(d) of the Act; (b) from issuers that have a worldwide market value of its outstanding common equity held by non-affiliates of $700 million or more; (c) from issuers that have outstanding securities that are notes, bonds, debentures, or evidence of indebtedness having a total remaining principal amount of at least $1 billion; (d) exempted securities as defined in Section 3(a)(12) of the Act; or (e) from issuers that are a government of a foreign country or a political subdivision of a foreign country.'' The Original Approval Order allows the fixed income portion of the portfolio excluding ABS and Private MBS, as defined below, to satisfy this 90% requirement.

[6] Rule 14.11(i)(4)(C)(iv)(b) provides that ''the aggregate gross notional value of listed derivatives based on any five or fewer underlying reference assets shall not exceed 65% of the weight of the portfolio (including gross notional exposures), and the aggregate gross notional value of listed derivatives based on any single underlying reference asset shall not exceed 30% of the weight of the portfolio (including gross notional exposures).'' The Exchange is proposing that the Fund would meet neither the 65% nor the 30% requirements of Rule 14.11(i)(4)(C)(iv)(b). Specifically, the Original Approval Order allows the Fund be exempt from this requirement as it relates to the Fund's holdings in futures and options (including options on futures) referencing Eurodollars and sovereign debt issued by the United States (*i.e.,* U.S. Department of Treasury Securities (''Treasury Securities'')) and other ''Group of Seven'' countries (Group of Seven or G–7 countries include the United States, Canada, France, Germany, Italy, Japan and the United Kingdom), where such futures and options contracts are listed on an exchange that is an Intermarket Surveillance Group (''ISG'') member or an exchange with which the Exchange has a comprehensive surveillance sharing agreement (''Eurodollar and G–7 Sovereign Futures and Options''). The Fund may also hold other listed derivatives, which will include only the following: Debt futures, interest rate futures, index futures, foreign exchange futures, equity options, equity futures, Treasury options, options on Treasury futures, interest rate swaps, foreign exchange options, foreign exchange swaps, credit default swaps (including single-name and index reference pools), loan credit default swap indices, and inflation-linked swaps, however such holdings will, when calculated independently of the Fund's holdings in Eurodollar and G–7 Sovereign Futures and Options, meet the requirements of Rule 14.11(i)(4)(C)(iv)(b).

[7] The Original Approval Order also allows the Fund to be issued certain equity instruments (''Equity Holdings'') that may not meet the requirements of Rule 14.11(i)(4)(C)(i). The Fund will not purchase such instruments and will dispose of such holdings as the Adviser determines is in the best interest of the Fund's shareholders. Such holdings will not constitute more than 10% of the Fund's net assets. The Adviser expects that the Fund will generally acquire such instruments through issuances that it receives by virtue of its other holdings, such as corporate actions or convertible securities.

[8] Rule 14.11(i)(4)(C)(ii)(a) provides that ''components that in the aggregate account for at least 75% of the fixed income weight of the portfolio must each have a minimum original principal amount outstanding of $100 million or more.'' The Exchange instead is proposing that the components that in the aggregate account for at

Continued

and Rule 14.11(i)(4)(C)(ii)(e).[9] Otherwise, the Fund will continue to comply with all other listing requirements applicable under the Original Approval Order on an initial and continued listing basis under Rule 14.11(i). As noted above, the Fund currently complies with the continued listing obligations applicable under the Original Approval Order and will continue to meet such obligations until and unless this proposal is approved.

The Fund is an actively managed exchange-traded fund that seeks a high level of current income by investing primarily in a diversified portfolio of high-, medium, and low-grade debt securities.[10] The Shares are offered by the Trust, which was established as a Delaware statutory trust. The Trust is registered with the Commission as an open-end investment company and has filed an effective registration statement on behalf of the Fund on Form N–1A (''Registration Statement'') with the Commission.[11]

Description of the Shares and the Fund

J.P Morgan Investment Management, Inc. is the investment adviser (the ''Adviser'') to the Fund. JPMorgan Chase Bank, N.A. is the administrator, custodian, and transfer agent for the Trust. JPMorgan Distribution Services, Inc. serves as the distributor (''Distributor'') for the Trust.

Rule 14.11(i)(7) provides that, if the investment adviser to the investment company issuing Managed Fund Shares is affiliated with a broker-dealer, such investment adviser shall erect and maintain a ''fire wall'' between the investment adviser and the broker-dealer with respect to access to information concerning the composition and/or changes to such investment company portfolio.[12] In addition, Rule 14.11(i)(7) further requires that personnel who make decisions on the investment company's portfolio composition must be subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the applicable investment company portfolio. Rule 14.11(i)(7) is similar to Rule 14.11(b)(5)(A)(i), however, Rule 14.11(i)(7) in connection with the establishment of a ''fire wall'' between the investment adviser and the broker-dealer reflects the applicable open-end fund's portfolio, not an underlying benchmark index, as is the case with index-based funds. The Adviser is not a registered broker-dealer, but is affiliated with multiple broker-dealers and has implemented and will maintain ''fire walls'' with respect to such broker-dealers regarding access to information concerning the composition and/or changes to the Fund's portfolio. In addition, Adviser personnel who make decisions regarding the Fund's portfolio are subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the Fund's portfolio. In the event that (a) the Adviser becomes registered as a broker-dealer or newly affiliated with another broker-dealer, or (b) any new adviser or sub-adviser is a registered broker-dealer or becomes affiliated with a broker-dealer, it will implement and maintain a fire wall with respect to its relevant personnel or such broker-dealer affiliate, as applicable, regarding access to information concerning the composition and/or changes to the portfolio, and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio.

The Fund intends to qualify each year as a regulated investment company under Subchapter M of the Internal Revenue Code of 1986, as amended.

JPMorgan Core Plus Bond ETF

According to the Registration Statement, the Fund is an actively managed exchange-traded fund that will seek a high level of current income by investing primarily in a diversified portfolio of high-, medium-, and low-grade debt securities. The Fund seeks to achieve its investment objective by investing, under Normal Market Conditions,[13] at least 80% of its net assets in Bonds.[14] The Adviser will invest across the credit spectrum to provide the Fund exposure to various credit ratings. Under Normal Market Conditions, at least 65% of the Fund's assets will be invested in securities that, at the time of purchase, are rated investment grade by a nationally recognized statistical rating organization or in securities that are unrated but are deemed by the Adviser to be of comparable quality. Among others, such securities include U.S. or foreign mortgage-backed securities (''MBS''), which are securities that represent direct or indirect participations in, or are collateralized and by and payable from, mortgage loans secured by real property and which may be issued or guaranteed by government-sponsored

least 60% of the fixed income weight of the portfolio will each have a minimum original principal outstanding of $100 million or more.

[9] Rule 14.11(i)(4)(C)(ii)(e) provides that ''non-agency, non-GSE and privately-issued mortgage-related and other asset-backed securities components of a portfolio shall not account, in the aggregate, for more than 20% of the weight of the fixed income portion of the portfolio,'' (the ''20% Restriction'') The Exchange is proposing that the Fund be permitted to hold up to 40% of the weight of the fixed income portion of the portfolio in non-agency, non-GSE and privately-issued mortgage-related and other asset-backed securities.

[10] The Fund plans to employ a strategy very similar to that currently employed by JPMorgan Core Plus Bond Fund, a mutual fund operated by the Adviser since March 5th, 1993.

[11] *See* Registration Statement on Form N–1A for the Trust, dated January 23, 2019 (File Nos. 333–191837 and 811–22903). The descriptions of the Fund and the Shares contained herein are based, in part, on information in the Registration Statement. The Commission has issued an order granting certain exemptive relief to the Trust under the Investment Company Act of 1940 (15 U.S.C. 80a–1) (''1940 Act'') (the ''Exemptive Order''). Investment Company Act Release No. 31990 (February 9, 2016) (File No. 812–13761).

[12] An investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940 (the ''Advisers Act''). As a result, the Adviser and its related personnel are subject to the provisions of Rule 204A–1 under the Advisers Act relating to codes of ethics. This Rule requires investment advisers to adopt a code of ethics that reflects the fiduciary nature of the relationship to clients as well as compliance with other applicable securities laws. Accordingly, procedures designed to prevent the communication and misuse of non-public information by an investment adviser must be consistent with Rule 204A–1 under the Advisers Act. In addition, Rule 206(4)–7 under the Advisers Act makes it unlawful for an investment adviser to provide investment advice to clients unless such investment adviser has (i) adopted and implemented written policies and procedures reasonably designed to prevent violation, by the investment adviser and its supervised persons, of the Advisers Act and the Commission rules adopted thereunder; (ii) implemented, at a minimum, an annual review regarding the adequacy of the policies and procedures established pursuant to subparagraph (i) above and the effectiveness of their implementation; and (iii) designated an individual (who is a supervised person) responsible for administering the policies and procedures adopted under subparagraph (i) above.

[13] As defined in Rule 14.11(i)(3)(E), the term ''Normal Market Conditions'' includes, but is not limited to, the absence of trading halts in the applicable financial markets generally; operational issues causing dissemination of inaccurate market information or system failures; or force majeure type events such as natural or man-made disaster, act of God, armed conflict, act of terrorism, riot or labor disruption, or any similar intervening circumstance. In response to adverse market, economic, or political conditions, the Fund reserves the right to invest in cash and Cash Equivalents, as defined below, without limitation, as determined by the Adviser.

[14] For purposes of this proposal, the term ''Bond'' includes only the following: Corporate bonds, U.S. government and agency debt securities, asset-backed securities, municipal securities, credit linked notes, participation notes, collateralized debt obligations, agency, non-agency and stripped mortgage-related and mortgage-backed securities (including adjustable rate mortgage loans), convertible securities (including contingent convertible securities), preferred stock, loan participations and assignments, commitments to loan assignments, variable and floating rate instruments, commercial paper, and foreign and emerging market debt securities. The Adviser intends to hold asset-backed securities, mortgage-related and mortgage-backed securities as part of a strategy designed to manage portfolio risk by diversifying away from corporate debt and to take advantage of certain market environments.

entities (''GSEs'') [15] such as Fannie Mae (formally known as the Federal National Mortgage Association) or Freddie Mac (formally known as the Federal Home Loan Mortgage Corporation) or issued or guaranteed by agencies of the U.S. government, such as the Government National Mortgage Association (''Ginnie Mae''); [16] and U.S. or foreign asset-backed securities (''ABS'').[17] Under Normal Market Conditions, the Fund will not invest more than 35% of its assets in securities rated below investment grade. The Fund's average weighted maturity will ordinarily range between five and twenty years.

Under Normal Market Conditions, the Fund may also invest up to 20% of its net assets in the following: Cash and certain Cash Equivalents [18] that are not otherwise captured under the definition of Bond, listed derivative instruments,[19] as described above, and OTC derivative instruments.[20] The Fund's holdings in Cash Equivalents and OTC derivative instruments will be in compliance with the limitations provided in Rules 14.11(i)(4)(C)(iii), 14.11(i)(4)(C)(v), respectively, and both listed and OTC derivative instruments will be in compliance with the limitations of Rule 14.11(i)(4)(C)(vi).[21]

The Fund's investments, including derivatives, will be consistent with the 1940 Act and the Fund's investment objective and policies and will not be used to enhance leverage (although certain derivatives and other investments may result in leverage).[22] That is, while the Fund will be permitted to borrow as permitted under the 1940 Act, the Fund's investments will not be used to seek performance that is the multiple or inverse multiple (*i.e.,* 2Xs and 3Xs) of the Fund's primary broad-based securities benchmark index (as defined in Form N–1A). The Fund will only use those derivatives described above. The Fund's use of derivative instruments will be collateralized.

Discussion

The Exchange submits this proposal because the Adviser does not expect that the Fund's fixed income securities holdings will meet all of the listing requirements applicable to the Shares under the Original Approval Order and Rule 14.11(i)(4)(C)(ii). The Fund will meet all requirements under Rule 14.11(i) except for those provided in the Original Approval Order [23] and those exceptions sought under this proposal, as described above, including Rule 14.11(i)(4)(C)(ii)(a) [24] and Rule 14.11(i)(4)(C)(ii)(e).

As it relates to Rule 14.11(i)(4)(C)(ii)(a), the Exchange is proposing only to reduce the weight of the fixed income portion of the portfolio that would need to have a minimum original principal amount outstanding of $100 million or more from 75% to 60%, which, based on the types of securities held by the Fund, it believes is not such a significant change in the composition of the fixed income portion of the portfolio as to meaningfully undercut the policy rationale underlying the rule, as outlined below. Rule 14.11(i)(4)(C)(ii)(a) is intended to ensure that the fixed income holdings of a series of Managed Fund Shares are sufficiently large as to prevent manipulation in the underlying holdings. The types of fixed income securities held by the Fund will often be in tranches of less than $100 million dollars, meaning that the securities would not be included for purposes of the calculation, however, many of such securities would be part of a deal with an underlying collateral pool well over a $100 million dollars, often greater than $500 million, making them less susceptible to manipulation than many other securities with a minimum original principal greater than $100 million. As such, the total deal size of many of the securities held by the Fund are significantly larger than the tranches on which the testing for the rule is based and would mitigate the concerns that rule 14.11(i)(4)(C)(ii)(a) is intended to address. Finally, the proposed change only represents a slight reduction to the applicable standard, which, combined

[15] A ''GSE'' is a type of financial services corporation created by the United States Congress. GSEs include Fannie Mae and Freddie Mac, but not Sallie Mae, which is no longer a government entity.

[16] For purposes of this proposal, MBS include only collateralized mortgage obligations (''CMOs''), which are debt obligations collateralized by mortgage loans or mortgage pass-through securities. Typically, CMOs are collateralized by Ginnie Mae, Fannie Mae or Freddie Mac certificates, but they may also be collateralized by whole loans or pass-through securities issued by private issuers (*i.e.,* issuers other than U.S. government agencies or GSEs) (''Private MBS''). Payments of principal and of interest on the mortgage-related instruments collateralizing the MBS, and any reinvestment income thereon, provide the funds to pay debt service on the CMOs. In a CMO, a series of bonds or certificates is issued in multiple classes. Each class of CMOs, often referred to as a ''tranche'' of securities, is issued at a specified fixed or floating coupon rate and has a stated maturity or final distribution date.

[17] ABS are securitized products in connection with which the securities issued, which may be issued by either a U.S. or a foreign entity, are collateralized by any type of financial asset, such as a consumer or student loan, a lease, or a secured or unsecured receivable. For purposes of this filing, ABS exclude: (i) MBS; (ii) a small business administration backed ABS traded ''To Be Announced'' or in a specified pool transaction as defined in FINRA Rule 6710(x); and (iii) U.S. or foreign collateralized debt obligations. As described above, the holdings of the Fund may not meet the 20% Restriction from Rule 14.11(i)(4)(C)(ii)(e), specifically in that the Fund's holdings in ABS and Private MBS (together, ''ABS and Private MBS'') may reach up to 40% of the weight of the fixed income portion of the Fund's portfolio.

[18] As defined in Exchange Rule 14.11(i)(4)(C)(iii)(b), Cash Equivalents are short-term instruments with maturities of less than three months, which includes only the following: (i) U.S. Government securities, including bills, notes, and bonds differing as to maturity and rates of interest, which are either issued or guaranteed by the U.S. Treasury or by U.S. Government agencies or instrumentalities; (ii) certificates of deposit issued against funds deposited in a bank or savings and loan association; (iii) bankers acceptances, which are short-term credit instruments used to finance commercial transactions; (iv) repurchase agreements and reverse repurchase agreements; (v) bank time deposits, which are monies kept on deposit with banks or savings and loan associations for a stated period of time at a fixed rate of interest; (vi) commercial paper, which are short-term unsecured promissory notes; and (vii) money market funds.

[19] *See* supra note 7 [sic].

[20] For purposes of this filing, OTC derivative instruments will include only the following: Index options, foreign exchange options, swaptions, credit default swaps (including single-name and index reference pools), foreign exchange swaps, loan credit default swap indices, inflation-linked swaps, interest rate swaps, non-dollar swaps, non-deliverable forward contracts and foreign exchange forward contracts.

[21] As noted above and allowed under the Original Approval Order, the Fund may by virtue of its Bond holdings be issued certain Equity Holdings that may not meet the requirements of Rule 14.11(i)(4)(C)(i). The Fund will not purchase Equity Holdings and, as such, they are excluded from both the 80% and the 20% buckets described above. The Fund will dispose of such holdings as the Adviser determines is in the best interest of the Fund's shareholders and such holdings will not constitute more than 10% of the Fund's net assets.

[22] The Fund will include appropriate risk disclosure in its offering documents, including leveraging risk. Leveraging risk is the risk that certain transactions of a fund, including a fund's use of derivatives, may give rise to leverage, causing a fund to be more volatile than if it had not been leveraged. To mitigate leveraging risk, the Fund will segregate or earmark liquid assets determined to be liquid by the Adviser in accordance with procedures established by the Trust's Board and in accordance with the 1940 Act (or, as permitted by applicable regulations, enter into certain offsetting positions) to cover its obligations under derivative instruments. These procedures have been adopted consistent with Section 18 of the 1940 Act and related Commission guidance. *See* 15 U.S.C. 80a–18; Investment Company Act Release No. 10666 (April 18, 1979), 44 FR 25128 (April 27, 1979); Dreyfus Strategic Investing, Commission No-Action Letter (June 22, 1987); Merrill Lynch Asset Management, L.P., Commission No-Action Letter (July 2, 1996).

[23] The Original Approval Order provides exceptions to Rule 14.11(i)(4)(C)(ii)(d), Rule 14.11(i)(4)(C)(iv)(b), and/or Rule 14.11(i)(4)(C)(i) for the Fund.

[24] Rule 14.11(i)(4)(C)(ii)(a) provides that ''components that in the aggregate account for at least 75% of the fixed income weight of the portfolio must each have a minimum original principal amount outstanding of $100 million or more.'' The Exchange instead is proposing that the components that in the aggregate account for at least 60% of the fixed income weight of the portfolio will each have a minimum original principal outstanding of $100 million or more.

with the other reasons described above, the Exchange believes will continue to mitigate the policy concerns that Rule 14.11(i)(4)(C)(ii)(a) is intended to address.

The Fund will also hold certain ABS and Private MBS in a manner that may not comply with Rule 14.11(i)(4)(C)(ii)(e). Such holdings are part of a strategy designed to manage the Fund's portfolio risk by diversifying away from corporate debt and to take advantage of certain market environments. This strategy will be actively managed by the Adviser and will adapt to both changing market environments and shifts in the underlying holdings of the Fund, but would be overly limited by the 20% Restriction under Rule 14.11(i)(4)(C)(ii)(e) that prevents the Fund from holding more than 20% of the fixed income portion of its portfolio in ABS and Private MBS. As such, the Exchange is proposing to allow the Fund to hold up to 40% of the weight of the fixed income portion of its portfolio in ABS and Private MBS. The Fund will utilize ABS and Private MBS as a means to diversify its portfolio of Bonds, which is intended to lower the volatility of the portfolio through a market cycle (typically three to five years). Greater exposure to the ABS and Private MBS would allow the Fund the flexibility to fully implement its risk mitigation strategy, while still limiting the Fund's holdings in ABS and Private MBS to 40% of the fixed income portion of the portfolio.

Further, because the Exchange is proposing to allow the Fund's holdings in ABS and Private MBS to increase (from 20% to 40% of the fixed income portion of the portfolio, as described above), the circumstances under which the exception to Rule 14.11(i)(4)(C)(ii)(d) was approved in the Original Approval Order are changing. The Original Approval Order provides that, instead of 90% of the weight of the Fund's holdings in fixed income securities meeting at least one of sub-paragraphs (a)–(e) in Rule 14.11(i)(4)(C)(ii)(d), Rule 14.11(i)(4)(C)(ii)(d) would apply only to the Fund's holdings in fixed income securities that are not ABS and Private MBS, which are currently limited to 20% of the fixed income portion of the portfolio by the 20% Restriction.

The Exchange believes that keeping this continued listing requirement from the Original Approval Order is consistent with the Act because the risk of manipulation of the Fund's investments in ABS and Private MBS are mitigated because the Adviser expects that all of its fixed income holdings will issue Statements to Noteholders on a no less frequent than quarterly basis.[25] Further, the Adviser represents that permitting limited investments in ABS and Private MBS, as described above, would be in the best interest of the Fund's shareholders because such investments have the potential to reduce the overall risk profile of the Fund's portfolio through diversification while ensuring that the policy concerns that Rule 14.11(i)(4)(C)(ii)(d) is intended to address are mitigated. As such, while the Fund will not technically meet the requirements of Rule 14.11(i)(4)(C)(ii)(d)(a), the policy concerns related to the transparency and availability of information regarding the fixed income securities held by a fund that the rule is intended to address are otherwise mitigated both by the availability of Statements to Noteholders.

In addition, the Exchange represents that: (1) Except as described above, the Fund will continue to satisfy all of the continued listing obligations applicable under the Original Approval Order; (2) the continued listing standards under Rule 14.11(i) will apply to the Shares of the Fund; (3) the Fund will adhere to its stated investment objective under Normal Market Conditions; and (4) the issuer of the Fund is required to comply with Rule 10A–3 [26] under the Act for the initial and continued listing of the Shares. In addition, the Exchange represents that the Fund will meet and be subject to all other requirements of the Generic Listing Standards and other applicable continued listing requirements for Managed Fund Shares under Exchange Rule 14.11(i), including those requirements regarding the Disclosed Portfolio (as defined in the Exchange rules) and the requirement that the Disclosed Portfolio and the net asset value (''NAV'') will be made available to all market participants at the same time,[27] intraday indicative value,[28] suspension of trading or removal,[29] trading halts,[30] disclosure,[31] and firewalls.[32]

The Shares

The Fund will issue and redeem Shares on a continuous basis at the NAV per Share only in large blocks of a specified number of Shares or multiples thereof (''Creation Units'') in transactions with authorized participants who have entered into agreements with the Distributor. A Creation Unit currently consists of 50,000 Shares, though this number may change from time to time. The exact number of Shares that will constitute a Creation Unit will be disclosed in the Registration Statement of the Fund. Once created, Shares of the Fund trade on the secondary market in amounts less than a Creation Unit.

Additional information regarding the Shares and the Fund, including investment strategies, risks, creation and redemption procedures, fees and expenses, portfolio holdings disclosure policies, distributions, taxes and reports to be distributed to beneficial owners of the Shares can be found in the Registration Statement or on the website for the Fund (*www.JPMorgan.com/etfs*), as applicable.

[25] While the Adviser expects that all of its fixed income holdings will issue Statements to Noteholders, it cannot guarantee that the holdings will issue Statements to Noteholders. While Rule 14.11(i)(4)(C)(ii)(d) subparagraph (a) includes in the 90% calculation all fixed income securities that are required to file reports pursuant to Sections 13 or 15(d) of the Act, many fixed income securities include in the bond indenture a requirement that the issuer make a public disclosure of a Statement to Noteholders even where they are not required to file such reports. Rule 14.11(i)(4)(C)(ii)(d) is intended to ensure that there is sufficient public information about the issuances and/or issuers of the fixed income securities held by a series of Managed Fund Shares. A Statement to Noteholders generally includes the same pieces of information about an issuer and issuance that would be included in Form 10D. Statements to Noteholders also typically include the following types of information: (1) The amount of the distribution(s) allocable to interest on the notes; (2) the amount of the distribution(s) allocable to principal of the notes; (3) the note balance, after taking into account all payments to be made on such distribution date; (4) the servicing fee paid and/or due but unpaid as of such distribution date; (5) the pool balance and required overcollateralization amount as of the close of business on the last day of the related collection period; (6) the reserve fund amount, the reserve fund required amount and the reserve fund draw amount; (7) the amount of the aggregate realized losses on the loans, if any, for the preceding collection period and the cumulative default ratio; (8) whether an amortization event will exist as of such distribution date; (9) the aggregate repurchase prices for loans, if any, that were repurchased by the seller during the related collection period; (10) the amount of fees payable to all parties pursuant to the indenture; (11) any and all other fees, expenses, indemnities or taxes payable by the issuer or the grantor trust (including reserved amounts for payments required to be made before the next distribution date); (12) the payments to the certificate holders; and (13) during a pre-funding period, the amount on deposit in the pre-funding account as of the close of business on the last day of the related collection period, and the pool balance of subsequent loans purchased during the related collection period, and following the pre-funding period, the amount of principal payments made on each class of notes from amounts on deposit in the pre-funding account.

[26] 17 CFR 240.10A–3.

[27] *See* Exchange Rules 14.11(i)(4)(A)(ii) and 14.11(i)(4)(B)(ii).

[28] *See* Exchange Rule 14.11(i)(4)(B)(i).

[29] *See* Exchange Rule 14.11(i)(4)(B)(iii).

[30] *See* Exchange Rule 14.11(i)(4)(B)(iv).

[31] *See* Exchange Rule 14.11(i)(6).

[32] *See* Exchange Rule 14.11(i)(7).

Availability of Information

As noted above, the Fund will comply with the requirements for Managed Fund Shares related to Disclosed Portfolio, NAV, and the Intraday Indicative Value, as defined in Rule 14.11(i)(3)(C). Additionally, the intra-day, closing and settlement prices of exchange-traded portfolio assets, including futures, listed swaps, listed options, and certain Equity Holdings, will be readily available from the exchanges on which such products are listed, automated quotation systems, published or other public sources, or online information services such as Bloomberg or Reuters. Quotation and last sale information for U.S. exchange-listed options contracts cleared by The Options Clearing Corporation will be available via the Options Price Reporting Authority. Intraday price quotations on Bonds, OTC derivative instruments, and OTC Equity Holdings are available from major broker-dealer firms and from third-parties, which may provide prices free with a time delay or in real-time for a paid fee. Price information for Cash Equivalents will be available from major market data vendors.

The Disclosed Portfolio will be available on the Fund's website (*www.jpmorgan.com/etfs*) free of charge. The Fund's website includes a form of the prospectus for the Fund and additional information related to NAV and other applicable quantitative information. Information regarding market price and trading volume of the Shares will be continuously available throughout the day on brokers' computer screens and other electronic services. Quotation and last sale information on the Shares will be available through the Consolidated Tape Association. Information regarding the previous day's closing price and trading volume for the Shares will be published daily in the financial section of newspapers. Trading in the Shares may be halted for market conditions or for reasons that, in the view of the Exchange, make trading inadvisable. The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. The Exchange has appropriate rules to facilitate trading in the shares during all trading sessions.

Surveillance

Trading of the Shares through the Exchange will be subject to the Exchange's surveillance procedures for derivative products, including Managed Fund Shares. All of the futures contracts and listed options contracts, as well as certain Equity Holdings held by the Fund will trade on markets that are a member of ISG or affiliated with a member of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.[33] The Exchange, FINRA, on behalf of the Exchange, or both will communicate regarding trading in the Shares and the underlying listed instruments, including listed derivatives and certain Equity Holdings, held by the Fund with the ISG, other markets or entities who are members or affiliates of the ISG, or with which the Exchange has entered into a comprehensive surveillance sharing agreement. In addition, the Exchange or FINRA may obtain information regarding trading in the Shares and the underlying listed instruments, including listed derivatives and certain Equity Holdings, held by the Fund from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. Additionally, the Exchange or FINRA, on behalf of the Exchange, are able to access, as needed, trade information for certain fixed income instruments reported to FINRA's Trade Reporting and Compliance Engine (''TRACE''). Trade price and other information relating to municipal securities is available through the Municipal Securities Rulemaking Board's (the ''MSRB'') Electronic Municipal Market Access (''EMMA'') system. All statements and representations made in this filing regarding the description of the portfolio or reference assets, limitations on portfolio holdings or reference assets, dissemination and availability of reference asset, and intraday indicative values, and the applicability of Exchange rules specified in this filing shall constitute continued listing requirements for the Fund. The issuer has represented to the Exchange that it will advise the Exchange of any failure by the Fund or the Shares to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will surveil for compliance with the continued listing requirements. If the Fund or the Shares are not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under Exchange Rule 14.12.

Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of the Fund. The Exchange will halt trading in the Shares under the conditions specified in Rule 11.18. Trading may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may include: (1) The extent to which trading is not occurring in the securities and/or the financial instruments composing the Disclosed Portfolio of the Fund; or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. Trading in the Shares also will be subject to Rule 14.11(i)(4)(B)(iv), which sets forth circumstances under which trading in the Shares of a Fund may be halted.

Trading Rules

The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. The Exchange allows trading in the Shares from 8:00 a.m. until 8:00 p.m. Eastern Time. The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions. As provided in Rule 11.11(a), the minimum price variation for quoting and entry of orders in Managed Fund Shares traded on the Exchange is $0.01, with the exception of securities that are priced less than $1.00, for which the minimum price variation for order entry is $0.0001.

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act[34] in general and Section 6(b)(5) of the Act[35] in particular in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange is proposing that the Fund will not meet Rule 14.11(i)(4)(C)(ii)(a), which requires that

[33] For a list of the current members and affiliate members of ISG, *see www.isgportal.com*. The Exchange notes that not all components of the Disclosed Portfolio for the Fund may trade on markets that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

[34] 15 U.S.C. 78f.

[35] 15 U.S.C. 78f(b)(5).

the at least 75% of the weight of the fixed income portion of a fund's portfolio has a minimum original principal amount outstanding of $100 million or more. Instead, the Exchange is proposing to reduce the weight of the fixed income portion of the portfolio from 75% to 60%, which, based on the types of securities held by the Fund, the Exchange believes is not such a significant change in the composition of the fixed income portion of the portfolio as to meaningfully undercut the policy rationale underlying the rule. Rule 14.11(i)(4)(C)(ii)(a) is intended to ensure that the fixed income holdings of a series of Managed Fund Shares are sufficiently large as to prevent manipulation in the underlying holdings. The types of fixed income securities held by the Fund will often be in tranches of less than $100 million dollars, meaning that the securities would not be included for purposes of the calculation, however, many of such securities would be part of a deal with an underlying collateral pool well over a $100 million dollars, often greater than $500 million, making them less susceptible to manipulation than many other securities with a minimum original principal greater than $100 million. As such, the total deal size of many of the securities held by the Fund are significantly larger than the tranches on which the testing for the rule is based and would mitigate the concerns that rule 14.11(i)(4)(C)(ii)(a) is intended to address. Finally, the proposed change only represents a slight reduction to the applicable standard, which, combined with the other reasons described above, the Exchange believes will continue to mitigate the policy concerns that Rule 14.11(i)(4)(C)(ii)(a) is intended to address.

The Fund will also hold certain ABS and Private MBS in a manner that may not comply with Rule 14.11(i)(4)(C)(ii)(e). Such holdings are part of a strategy designed to manage the Fund's portfolio risk by diversifying away from corporate debt and to take advantage of certain market environments. This strategy will be actively managed by the Adviser and will adapt to both changing market environments and shifts in the underlying holdings of the Fund, but would be overly limited by the 20% Restriction under Rule 14.11(i)(4)(C)(ii)(e) that prevents the Fund from holding more than 20% of the fixed income portion of its portfolio in ABS and Private MBS. As such, the Exchange is proposing to allow the Fund to hold up to 40% of the weight of the fixed income portion of its portfolio in ABS and Private MBS. The Fund will utilize ABS and Private MBS as a means to diversify its portfolio of Bonds, which is intended to lower the volatility of the portfolio through a market cycle (typically three to five years). Greater exposure to the ABS and Private MBS would allow the Fund the flexibility to fully implement its risk mitigation strategy, while still limiting the Fund's holdings in ABS and Private MBS to 40% of the fixed income portion of the portfolio.

Further, because the Exchange is proposing to allow the Fund's holdings in ABS and Private MBS to increase (from 20% to 40% of the fixed income portion of the portfolio, as described above), the circumstances under which the exception to Rule 14.11(i)(4)(C)(ii)(d) was approved in the Original Approval Order are changing. The Original Approval Order provides that, instead of 90% of the weight of the Fund's holdings in fixed income securities meeting at least one of sub-paragraphs (a)–(e) in Rule 14.11(i)(4)(C)(ii)(d), Rule 14.11(i)(4)(C)(ii)(d) would apply only to the Fund's holdings in fixed income securities that are not ABS and Private MBS, which are currently limited to 20% of the fixed income portion of the portfolio by the 20% Restriction.

The Exchange believes that keeping this continued listing requirement from the Original Approval Order is consistent with the Act because the risk of manipulation of the Fund's investments in ABS and Private MBS are mitigated because the Adviser expects that all of its fixed income holdings will issue Statements to Noteholders on a no less frequent than quarterly basis.[36] Further, the Adviser represents that permitting limited investments in ABS and Private MBS, as described above, would be in the best interest of the Fund's shareholders because such investments have the potential to reduce the overall risk profile of the Fund's portfolio through diversification while ensuring that the policy concerns that Rule 14.11(i)(4)(C)(ii)(d) is intended to address are mitigated. As such, while the Fund will not technically meet the requirements of Rule 14.11(i)(4)(C)(ii)(d)(a), the policy concerns related to the transparency and availability of information regarding the fixed income securities held by a fund that the rule is intended to address are otherwise mitigated both by the availability of Statements to Noteholders.

In addition, the Exchange represents that: (1) Except as described above, the Fund will continue to satisfy all of the continued listing obligations applicable under the Original Approval Order; (2) the continued listing standards under Rule 14.11(i) will apply to the Shares of the Fund; (3) the Fund will adhere to its stated investment objective under Normal Market Conditions; and (4) the issuer of the Fund is required to comply with Rule 10A–3 [37] under the Act for the initial and continued listing of the Shares. In addition, the Exchange represents that the Fund will meet and be subject to all other requirements of the Generic Listing Standards and other applicable continued listing requirements for Managed Fund Shares under Exchange Rule 14.11(i), including those requirements regarding the Disclosed Portfolio (as defined in the Exchange rules) and the requirement that the Disclosed Portfolio and the net asset value (''NAV'') will be made available to all market participants at

[36] While the Adviser expects that all of its fixed income holdings will issue Statements to Noteholders, it cannot guarantee that the holdings will issue Statements to Noteholders. While Rule 14.11(i)(4)(C)(ii)(d) subparagraph (a) includes in the 90% calculation all fixed income securities that are required to file reports pursuant to Sections 13 or 15(d) of the Act, many fixed income securities include in the bond indenture a requirement that the issuer make a public disclosure of a Statement to Noteholders even where they are not required to file such reports. Rule 14.11(i)(4)(C)(ii)(d) is intended to ensure that there is sufficient public information about the issuances and/or issuers of the fixed income securities held by a series of Managed Fund Shares. A Statement to Noteholders generally includes the same pieces of information about an issuer and issuance that would be included in Form 10D. Statements to Noteholders also typically include the following types of information: (1) The amount of the distribution(s) allocable to interest on the notes; (2) the amount of the distribution(s) allocable to principal of the notes; (3) the note balance, after taking into account all payments to be made on such distribution date; (4) the servicing fee paid and/or due but unpaid as of such distribution date; (5) the pool balance and required overcollateralization amount as of the close of business on the last day of the related collection period; (6) the reserve fund amount, the reserve fund required amount and the reserve fund draw amount; (7) the amount of the aggregate realized losses on the loans, if any, for the preceding collection period and the cumulative default ratio; (8) whether an amortization event will exist as of such distribution date; (9) the aggregate repurchase prices for loans, if any, that were repurchased by the seller during the related collection period; (10) the amount of fees payable to all parties pursuant to the indenture; (11) any and all other fees, expenses, indemnities or taxes payable by the issuer or the grantor trust (including reserved amounts for payments required to be made before the next distribution date); (12) the payments to the certificate holders; and (13) during a pre-funding period, the amount on deposit in the pre-funding account as of the close of business on the last day of the related collection period, and the pool balance of subsequent loans purchased during the related collection period, and following the pre-funding period, the amount of principal payments made on each class of notes from amounts on deposit in the pre-funding account.

[37] 17 CFR 240.10A–3.

the same time,[38] intraday indicative value,[39] suspension of trading or removal,[40] trading halts,[41] disclosure,[42] and firewalls.[43]

The Exchange further believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will continue to be listed and traded on the Exchange pursuant to the continued listing criteria in Rule 14.11(i). The Exchange believes that its surveillance procedures are adequate to properly monitor the trading of the Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities laws. Rule 14.11(i)(7) provides that, if the investment adviser to the investment company issuing Managed Fund Shares is affiliated with a broker-dealer, such investment adviser shall erect a ''fire wall'' between the investment adviser and the broker-dealer with respect to access to information concerning the composition and/or changes to such investment company portfolio. The Adviser is not a registered broker-dealer, but is affiliated with multiple broker-dealers and has implemented and will maintain ''fire walls'' with respect to such broker-dealers regarding access to information concerning the composition and/or changes to the Fund's portfolio. In addition, Adviser personnel who make decisions regarding the Fund's portfolio are subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the Fund's portfolio. All of the futures contracts and listed options contracts, as well as certain Equity Holdings held by the Fund will trade on markets that are a member of ISG or affiliated with a member of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.[44] The Exchange, FINRA, on behalf of the Exchange, or both may obtain information and will communicate regarding trading in the Shares and the underlying listed instruments, including listed derivatives and certain Equity Holdings, held by the Fund with the ISG, other markets or entities who are members or affiliates of the ISG, or with which the Exchange has entered into a comprehensive surveillance sharing agreement. Additionally, the Exchange or FINRA, on behalf of the Exchange, are able to access, as needed, trade information for certain fixed income instruments reported to FINRA's TRACE. Trade price and other information relating to municipal securities is available through the MSRB EMMA system.

According to the Registration Statement, the Fund will invest, under Normal Market Conditions, at least 80% of its net assets in Bonds. Additionally, the Fund may hold up to an aggregate amount of 15% of its net assets in illiquid assets (calculated at the time of investment), as deemed illiquid by the Adviser under the 1940 Act.[45] The Fund will monitor its portfolio liquidity on an ongoing basis to determine whether, in light of current circumstances, an adequate level of liquidity is being maintained, and will consider taking appropriate steps in order to maintain adequate liquidity if, through a change in values, net assets, or other circumstances, more than 15% of the Fund's net assets are held in illiquid assets. Illiquid assets include securities subject to contractual or other restrictions on resale and other instruments that lack readily available markets as determined in accordance with Commission staff guidance.

The proposed rule change is designed to promote just and equitable principles of trade and to protect investors and the public interest in that the Exchange will obtain a representation from the issuer of the Shares that the NAV per Share will be calculated daily and that the NAV and the Disclosed Portfolio will be made available to all market participants at the same time. In addition, a large amount of information is publicly available regarding the Fund and the Shares, thereby promoting market transparency. Moreover, the Intraday Indicative Value will be disseminated by one or more major market data vendors at least every 15 seconds during Regular Trading Hours. On each business day, before commencement of trading in Shares during Regular Trading Hours, the Fund will disclose on its website the Disclosed Portfolio that will form the basis for the Fund's calculation of NAV at the end of the business day. The Fund's website will include additional quantitative information updated on a daily basis, including, for the Fund: (1) The prior business day's NAV and the market closing price or mid-point of the Bid/Ask Price,[46] and a calculation of the premium or discount of the market closing price or Bid/Ask Price against the NAV; and (2) data in chart format displaying the frequency distribution of discounts and premiums of the daily market closing price or Bid/Ask Price against the NAV, within appropriate ranges, for each of the four previous calendar quarters. Additionally, information regarding market price and trading of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services, and quotation and last sale information for the Shares will be available on the facilities of the Consolidated Tape Association. The website for the Fund will include a form of the prospectus for the Fund and additional data relating to NAV and other applicable quantitative information. Trading in Shares of a Fund will be halted under the conditions specified in Rule 11.18. Trading may also be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. Finally, trading in the Shares will be subject to Rule 14.11(i)(4)(B)(iv), which sets forth circumstances under which Shares may be halted. In addition, as noted above, investors will have ready access to information regarding the Fund's holdings, the Intraday Indicative Value, the Disclosed Portfolio, and quotation and last sale information for the Shares.

Additionally, the intra-day, closing and settlement prices of exchange-traded portfolio assets, including futures, swaps, listed options, and certain Equity Holdings, will be readily available from the exchanges on which such products are listed, automated quotation systems, published or other

[38] *See* Exchange Rules 14.11(i)(4)(A)(ii) and 14.11(i)(4)(B)(ii).

[39] *See* Exchange Rule 14.11(i)(4)(B)(i).

[40] *See* Exchange Rule 14.11(i)(4)(B)(iii).

[41] *See* Exchange Rule 14.11(i)(4)(B)(iv).

[42] *See* Exchange Rule 14.11(i)(6).

[43] *See* Exchange Rule 14.11(i)(7).

[44] For a list of the current members and affiliate members of ISG, *see www.isgportal.com*. The Exchange notes that not all components of the Disclosed Portfolio for the Fund may trade on markets that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

[45] The Commission has stated that long-standing Commission guidelines have required open-end funds to hold no more than 15% of their net assets in illiquid securities and other illiquid assets. *See* Investment Company Act Release No. 28193 (March 11, 2008), 73 FR 14618 (March 18, 2008), footnote 34. *See also,* Investment Company Act Release No. 5847 (October 21, 1969), 35 FR 19989 (December 31, 1970) (Statement Regarding ''Restricted Securities''); Investment Company Act Release No. 18612 (March 12, 1992), 57 FR 9828 (March 20, 1992) (Revisions of Guidelines to Form N–1A). A fund's portfolio security is illiquid if it cannot be disposed of in the ordinary course of business within seven days at approximately the value ascribed to it by the fund. *See* Investment Company Act Release No. 14983 (March 12, 1986), 51 FR 9773 (March 21, 1986) (adopting amendments to Rule 2a–7 under the 1940 Act); Investment Company Act Release No. 17452 (April 23, 1990), 55 FR 17933 (April 30, 1990) (adopting Rule 144A under the Securities Act of 1933).

[46] The Bid/Ask Price of a Fund will be determined using the highest bid and the lowest offer on the Exchange as of the time of calculation of the Fund's NAV. The records relating to Bid/Ask Prices will be retained by the Fund or its service providers.

public sources, or online information services such as Bloomberg or Reuters. Quotation and last sale information for U.S. exchange-listed options contracts cleared by The Options Clearing Corporation will be available via the Options Price Reporting Authority. Intraday price quotations on Bonds, OTC derivative instruments, and OTC Equity Holdings are available from major broker-dealer firms and from third-parties, which may provide prices free with a time delay or in real-time for a paid fee. Price information for Cash Equivalents will be available from major market data vendors.

The proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest in that it will facilitate the listing and trading of an additional type of actively-managed exchange traded product that will enhance competition among market participants, to the benefit of investors and the marketplace. As noted above, the Exchange has in place surveillance procedures relating to trading in the Shares and may obtain information via ISG, from other exchanges that are members of ISG, or with which the Exchange has entered into a comprehensive surveillance sharing agreement. In addition, the Exchange, or FINRA, on behalf of the Exchange, is able to access, as needed, trade information for certain fixed income instruments reported to TRACE and the MSRB EMMA system. As noted above, investors will also have ready access to information regarding the Fund's holdings, the Intraday Indicative Value, the Disclosed Portfolio, and quotation and last sale information for the Shares.

For the above reasons, the Exchange believes that the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purpose of the Act. The Exchange notes that the proposed rule change will allow the Adviser to fully implement its investment strategy, which will enhance competition among market participants, to the benefit of investors and the marketplace.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

A. By order approve or disapprove such proposed rule change, or

B. institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–CboeBZX–2019–044 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CboeBZX–2019–044. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CboeBZX–2019–044, and should be submitted on or before June 24, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[47]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–11447 Filed 5–31–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission Office of FOIA Services 100 F Street NE, Washington, DC 20549–2736

Extension:

Rule 19b–5 and Form PILOT, SEC File No. 270–448, OMB Control No. 3235–0507

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''SEC'') is soliciting comments on the existing collection of information provided for in Rule 19b–5 (17 CFR 240.19b–5) and Form PILOT (17 CFR 249.821) under the Securities Exchange Act of 1934 (''Exchange Act'') (15 U.S.C. 78a *et seq.*). The SEC plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 19b–5 provides a temporary exemption from the rule-filing requirements of Section 19(b) of the Exchange Act (15 U.S.C. 78s(b)) to self-regulatory organizations (''SROs'') wishing to establish and operate pilot trading systems. Rule 19b–5 permits an SRO to develop a pilot trading system and to begin operation of such system

[47] 17 CFR 200.30–3(a)(12).

shortly after submitting an initial report on Form PILOT to the SEC. During operation of any such pilot trading system, the SRO must submit quarterly reports of the system's operation to the SEC, as well as timely amendments describing any material changes to the system. Within two years of operating such pilot trading system under the exemption afforded by Rule 19b–5, the SRO must submit a rule filing pursuant to Section 19(b)(2) of the Exchange Act (15 U.S.C. 78s(b)(2)) to obtain permanent approval of the pilot trading system from the SEC.

The collection of information is designed to allow the SEC to maintain an accurate record of all new pilot trading systems operated by SROs and to determine whether an SRO has properly availed itself of the exemption afforded by Rule 19b–5, is operating a pilot trading system in compliance with the Exchange Act, and is carrying out its statutory oversight obligations under the Exchange Act.

The respondents to the collection of information are national securities exchanges and national securities associations.

There are 23 SROs which could avail themselves of the exemption under Rule 19b–5 and the use of Form PILOT. The SEC estimates that approximately three of these SROs, in the aggregate, each year will file on Form PILOT one initial report (*i.e.,* 3 reports total, for an estimated annual burden of 72 hours total), four quarterly reports (*i.e.,* 12 reports total, for an estimated annual burden of 36 hours total), and two amendments (*i.e.,* 6 reports total, for an estimated annual burden of 18 hours total). Thus, the estimated annual response burden resulting from Form PILOT is 42 hours per SRO, or a total of 126 hours for the three SROs. The SEC estimates that the aggregate annual internal cost of compliance for all three respondents is approximately $38,094 (126 hours at an average of $302.333 per hour). In addition, the SEC estimates that the three SRO respondents will incur, in the aggregate, printing, supplies, copying, and postage expenses of $6,101 per year for filing initial reports, $3,046 per year for filing quarterly reports, and $1,523 per year for filing notices of material systems changes, for a total annual cost burden of $10,670 for all three respondents.

Written comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the SEC, including whether the information shall have practical utility; (b) the accuracy of the SEC's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: Charles Riddle, Acting Director/Chief Information Officer, Securities and Exchange Commission, c/o Candace Kenner, 100 F Street NE, Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov*.

Dated: May 28, 2019.

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–11433 Filed 5–31–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 33493; 812–14917]

John Hancock GA Mortgage Trust, et al.

May 28, 2019.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of application for an order under sections 17(d) and 57(i) of the Investment Company Act of 1940 (the ''Act'') and rule 17d–1 under the Act to permit certain joint transactions otherwise prohibited by sections 17(d) and 57(a)(4) of the Act and rule 17d–1 under the Act. Applicants request an order to permit certain closed-end investment companies and business development companies to co-invest in portfolio companies with affiliated investment funds.

APPLICANTS: John Hancock GA Mortgage Trust (''Mortgage Trust''), John Hancock GA Private Placement Trust (''Private Placement Trust''), John Hancock GA Senior Loan Trust (''Senior Loan Trust''), Hancock Capital Investment Management, LLC (''HCIM''), John Hancock Life Insurance Company (U.S.A.), John Hancock Life & Health Insurance Company, John Hancock Life Insurance Company of New York, John Hancock Funding Company, LLC, Hancock Mortgage REIT, Inc., and Hancock Mortgage REIT II, Inc.

FILING DATES: The application was filed on June 8, 2018, and amended on November 1, 2018, March 22, 2019, and May 22, 2019.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on June 24, 2019, 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: Secretary, U.S. Securities and Exchange Commission, 100 F St. NE, Washington, DC 20549–1090. Applicants: 197 Clarendon Street, C–03, Boston, MA 02116.

FOR FURTHER INFORMATION CONTACT: Nick Cordell, Senior Counsel, at (202) 551–5496, or Aaron Gilbride, Branch Chief, at (202) 551–6906 (Chief Counsel's Office, Division of Investment Management).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete 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.

Introduction

1. The Applicants request an order of the Commission under Sections 17(d) and 57(i) and Rule 17d–1 thereunder (the ''Order'') to permit, subject to the terms and conditions set forth in the application (the ''Conditions''), a Regulated Fund [1] and one or more other

[1] ''Regulated Funds'' means Mortgage Trust, Private Placement Trust, Senior Loan Trust, and any Future Regulated Funds. ''Future Regulated Fund'' means a closed-end management investment company (a) that is registered under the Act or has elected to be regulated as a BDC, (b) whose investment adviser is an Adviser and (c) that intends to participate in the Co-Investment Program. ''Adviser'' means HCIM together with any future investment adviser that (i) controls, is controlled by or is under common control with

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Regulated Funds and/or one or more Affiliated Funds [2] to enter into Co-Investment Transactions with each other. ''Co-Investment Transaction'' means any transaction in which one or more Regulated Funds (or its Wholly-Owned Investment Sub) [3] participated together with one or more Affiliated Funds and/or one or more other Regulated Funds in reliance on the Order. ''Potential Co-Investment Transaction'' means any investment opportunity in which a Regulated Fund (or its Wholly-Owned Investment Sub) could not participate together with one or more Affiliated Funds and/or one or more other Regulated Funds without obtaining and relying on the Order.[4]

Applicants

2. Mortgage Trust is a Delaware statutory trust that will register with the Commission under the Act as a closed-end, non-diversified management investment company. All of the investors in Mortgage Trust will be insurance companies that are wholly-owned by MFC. Mortgage Trust's Board [5] will be comprised of a majority of members who are Independent Directors.[6]

3. Private Placement Trust is a Delaware statutory trust that will register with the Commission under the Act as a closed-end, non-diversified management investment company. All of the investors in Private Placement Trust will be insurance companies that are wholly-owned by MFC. Private Placement Trust's Board will be comprised of a majority of members who are Independent Directors.

4. Senior Loan Trust is a Delaware statutory trust that will register with the Commission under the Act as a closed-end, non-diversified management investment company. All of the investors in Senior Loan Trust will be insurance companies that are wholly-owned by MFC. Senior Loan Trust's Board will be comprised of a majority of members who are Independent Directors.

5. HCIM, a Delaware limited liability company that is registered under the Advisers Act, will serve as the investment adviser to each of the Existing Regulated Funds and serves as the investment advisers to the Existing Affiliated Funds, and to certain asset classes of the MFC Accounts.

6. The Existing Affiliated Funds are Hancock Mortgage REIT, Inc., and Hancock Mortgage REIT II, Inc. Applicants represent that each Existing Affiliated Fund is a separate and distinct legal entity and each would be an investment company but for Section 3(c)(5)(C) of the Act.

7. Each of the Applicants may be deemed to be directly or indirectly controlled by MFC, a Canadian corporation. All of the investors in each Regulated Fund are insurance companies that are wholly-owned by MFC. Additionally, HCIM is an indirect wholly-owned subsidiary of MFC. Thus, MFC may be deemed to control the Regulated Funds and the Affiliated Funds. Applicants state that MFC is a life insurance company incorporated under the Insurance Company Act (Canada) and does not currently offer investment advisory services to any person and is not expected to do so in the future. Applicants state that as a result, MFC has not been included as an Applicant.

8. Applicants state that a Regulated Fund may, from time to time, form one or more Wholly-Owned Investment Subs. Such a subsidiary may be prohibited from investing in a Co-Investment Transaction with a Regulated Fund (other than its parent) or any Affiliated Fund because it would be a company controlled by its parent Regulated Fund for purposes of Section 57(a)(4) and Rule 17d–1. Applicants request that each Wholly-Owned Investment Sub be permitted to participate in Co-Investment Transactions in lieu of the Regulated Fund that owns it and that the Wholly-Owned Investment Sub's participation in any such transaction be treated, for purposes of the Order, as though the parent Regulated Fund were participating directly. Applicants represent that this treatment is justified because a Wholly-Owned Investment Sub would have no purpose other than serving as a holding vehicle for the Regulated Fund's investments and, therefore, no conflicts of interest could arise between the parent Regulated Fund and the Wholly-Owned Investment Sub. The Board of the parent Regulated Fund would make all relevant determinations under the Conditions with regard to a Wholly-Owned Investment Sub's participation in a Co-Investment Transaction, and the Board would be informed of, and take into consideration, any proposed use of a Wholly-Owned Investment Sub in the Regulated Fund's place. If the parent Regulated Fund proposes to participate in the same Co-Investment Transaction with any of its Wholly-Owned Investment Subs, the Board of the parent Regulated Fund will also be informed of, and take into consideration, the relative participation of the Regulated Fund and the Wholly-Owned Investment Sub.

Applicants' Representations

A. Allocation Process

9. Applicants state that the Adviser is presented with a substantial number of investment opportunities each year on behalf of its clients and will determine how to allocate those opportunities in a manner that, over time, is fair and equitable to all of its clients. Such investment opportunities may be Potential Co-Investment Transactions.

10. Applicants represent that the Adviser has established processes for

HCIM and (ii) is registered as an investment adviser under the Investment Advisers Act of 1940 (the ''Advisers Act''), and (iii) is not a Regulated Fund or a subsidiary of a Regulated Fund.

[2] ''Affiliated Fund'' means any Existing Affiliated Funds, the MFC Accounts, and any entity (a) whose investment adviser is an Adviser, (b) that either (x) would be an investment company but for Section 3(c)(1), 3(c)(3), 3(c)(5)(C) or 3(c)(7) of the Act or (y) relies on Rule 3a–7 under the Act, and (c) that intends to participate in the Co-Investment Program. ''Existing Affiliated Funds'' means Hancock Mortgage REIT, Inc., and Hancock Mortgage REIT II, Inc. ''MFC Accounts'' means John Hancock Life Insurance Company (U.S.A.), John Hancock Life & Health Insurance Company, John Hancock Life Insurance Company of New York, and any future direct or indirect wholly-owned or majority-owned subsidiaries of Manulife Financial Corporation (''MFC'') that intend to participate in Co-Investment Transactions. ''Co-Investment Program'' means the proposed co-investment program that would permit one or more Regulated Funds and/or one or more Affiliated Funds to participate in the same investment opportunities where such participation would otherwise be prohibited under Section 57(a)(4)and Rule 17d–1 by (a) co-investing with each other in securities issued by issuers in private placement transactions in which an Adviser negotiates terms in addition to price, and (b) making Follow-On Investments (as defined below). The term ''private placement transactions'' means transactions in which the offer and sale of securities by the issuer are exempt from registration under the Securities Act of 1933 (the ''Securities Act'').

[3] ''Wholly-Owned Investment Sub'' means an entity (i) that is wholly-owned by a Regulated Fund (with such Regulated Fund at all times holding, beneficially and of record, 100% of the voting and economic interests); (ii) whose sole business purpose is to hold one or more investments on behalf of such Regulated Fund; (iii) with respect to which such Regulated Fund's Board (defined below) has the sole authority to make all determinations with respect to the entity's participation under the Conditions; and (iv) that would either (a) be an investment company but for Section 3(c)(1) or 3(c)(7) of the Act, or (b) relied on Rule 3a–7 under the Act.

[4] All existing entities that currently intend to rely on the Order have been named as Applicants and any existing or future entities that may rely on the Order in the future will comply with its terms and Conditions set forth in the application.

[5] ''Board'' means the board of directors (or the equivalent) of a Regulated Fund.

[6] ''Independent Director'' means a member of the Board of any relevant entity who is not an ''interested person'' as defined in Section 2(a)(19) of the Act. No Independent Director of a Regulated Fund will have a financial interest in any Co-Investment Transaction, other than indirectly through share ownership in one of the Regulated Funds.

allocating initial investment opportunities, opportunities for subsequent investments in an issuer and dispositions of securities holdings reasonably designed to treat all clients fairly and equitably. Further, Applicants represent that these processes will be extended and modified in a manner reasonably designed to ensure that the additional transactions permitted under the Order will both (i) be fair and equitable to the Regulated Funds and the Affiliated Funds and (ii) comply with the Conditions.

11. Specifically, applicants state that the Adviser is organized and managed such that the relevant portfolio management teams (''Investment Teams'') responsible for evaluating investment opportunities and making investment decisions on behalf of clients are promptly notified of the opportunities. If the requested Order is granted, the Adviser will establish, maintain and implement policies and procedures reasonably designed to ensure that, when such opportunities arise, the Adviser to the relevant Regulated Funds are promptly notified and receive the same information about the opportunity as any other Adviser considering the opportunity for their clients. In particular, consistent with Condition 1, if a Potential Co-Investment Transaction falls within the then-current Objectives and Strategies [7] and any Board-Established Criteria [8] of a Regulated Fund, the policies and procedures will require that the relevant Investment Team responsible for that Regulated Fund receive sufficient information to allow the Regulated Fund's Adviser to make its independent determination and recommendations under the Conditions.

12. The Adviser to each applicable Regulated Fund will then make an independent determination of the appropriateness of the investment for the Regulated Fund in light of the Regulated Fund's then-current circumstances. If the Adviser to a Regulated Fund deems the Regulated Fund's participation in such Potential Co-Investment Transaction to be appropriate, then it will formulate a recommendation regarding the proposed order amount for the Regulated Fund.

13. Applicants state that, for each Regulated Fund and Affiliated Fund whose Adviser recommends participating in a Potential Co-Investment Transaction, the applicable Investment Team will approve the investment and the investment amount, and will coordinate an order submission process with a designated representative of each applicable Investment Team of a Regulated Fund and Affiliated Fund. Applicants state further that, at this stage, each proposed order amount may be reviewed and adjusted, in accordance with the applicable Adviser's written allocation policies and procedures.[9] The order of a Regulated Fund or Affiliated Fund resulting from this process is referred to as its ''Internal Order.'' The final Internal Order will be submitted for approval by the Required Majority of any participating Regulated Funds in accordance with the Conditions.[10]

14. If the aggregate Internal Orders for a Potential Co-Investment Transaction do not exceed the size of the investment opportunity immediately prior to the submission of the orders to the underwriter, broker, dealer or issuer, as applicable (the ''External Submission''), then each Internal Order will be fulfilled as placed. If, on the other hand, the aggregate Internal Orders for a Potential Co-Investment Transaction exceed the size of the investment opportunity immediately prior to the External Submission, then the allocation of the opportunity will be made pro rata on the basis of the size of the Internal Orders.[11] If, subsequent to such External Submission, the size of the opportunity is increased or decreased, or if the terms of such opportunity, or the facts and circumstances applicable to the Regulated Funds' or the Affiliated Funds' consideration of the opportunity, change, the participants will be permitted to submit revised Internal Orders in accordance with written allocation policies and procedures that the Advisers will establish, implement and maintain.[12]

B. Follow-On Investments

15. Applicants state that from time to time the Regulated Funds and Affiliated Funds may have opportunities to make Follow-On Investments [13] in an issuer in which a Regulated Fund and one or more other Regulated Funds and/or Affiliated Funds previously have invested.

16. Applicants propose that Follow-On Investments would be divided into two categories depending on whether the prior investment was a Co-Investment Transaction or a Pre-Boarding Investment.[14] If the Regulated

[7] ''Objectives and Strategies'' means with respect to any Regulated Fund, its investment objectives and strategies, as described in its most current registration statement on Form N–2, other current filings with the Commission under the Securities Act of 1933 (the ''Securities Act'') or under the Securities Exchange Act of 1934, as amended, and its most current report to stockholders.

[8] ''Board-Established Criteria'' means criteria that the Board of a Regulated Fund may establish from time to time to describe the characteristics of Potential Co-Investment Transactions regarding which the Adviser to the Regulated Fund should be notified under Condition 1. The Board-Established Criteria will be consistent with the Regulated Fund's Objectives and Strategies. If no Board-Established Criteria are in effect, then the Regulated Fund's Adviser will be notified of all Potential Co-Investment Transactions that fall within the Regulated Fund's then-current Objectives and Strategies. Board-Established Criteria will be objective and testable, meaning that they will be based on observable information, such as industry/sector of the issuer, minimum EBITDA of the issuer, asset class of the investment opportunity or required commitment size, and not on characteristics that involve a discretionary assessment. The Adviser to the Regulated Fund may from time to time recommend criteria for the Board's consideration, but Board-Established Criteria will only become effective if approved by a majority of the Independent Directors. The Independent Directors of a Regulated Fund may at any time rescind, suspend or qualify its approval of any Board-Established Criteria, though Applicants anticipate that, under normal circumstances, the Board would not modify these criteria more often than quarterly.

[9] The reason for any such adjustment to a proposed order amount will be documented in writing and preserved in the records of the Advisers.

[10] ''Required Majority'' means a required majority, as defined in Section 57(o) of the Act. In the case of a Regulated Fund that is a registered closed-end fund, the Board members that make up the Required Majority will be determined as if the Regulated Fund were a BDC subject to Section 57(o).

[11] The Advisers will maintain records of all proposed order amounts, Internal Orders and External Submissions in conjunction with Potential Co-Investment Transactions. Each applicable Adviser will provide the Eligible Directors with information concerning the Affiliated Funds' and Regulated Funds' order sizes to assist the Eligible Directors with their review of the applicable Regulated Fund's investments for compliance with the Conditions. ''Eligible Directors'' means, with respect to a Regulated Fund and a Potential Co-Investment Transaction, the members of the Regulated Fund's Board eligible to vote on that Potential Co-Investment Transaction under Section 57(o) of the Act.

[12] However, if the size of the opportunity is decreased such that the aggregate of the original Internal Orders would exceed the amount of the remaining investment opportunity, then upon submitting any revised order amount to the Board of a Regulated Fund for approval, the Adviser to the Regulated Fund will also notify the Board promptly of the amount that the Regulated Fund would receive if the remaining investment opportunity were allocated pro rata on the basis of the size of the original Internal Orders. The Board of the Regulated Fund will then either approve or disapprove of the investment opportunity in accordance with condition 2, 6, 7, 8 or 9, as applicable.

[13] ''Follow-On Investment'' means an additional investment in the same issuer, including, but not limited to, through the exercise of warrants, conversion privileges or other rights to purchase securities of the issuer.

[14] ''Pre-Boarding Investments'' are investments in an issuer held by a Regulated Fund as well as one or more Affiliated Funds and/or one or more other Regulated Funds that were acquired prior to participating in any Co-Investment Transaction: (i) In transactions in which the only term negotiated by or on behalf of such funds was price in reliance on one of the JT No-Action Letters (defined below); (ii) in transactions occurring at least 90 days apart and without coordination between the Regulated Fund and any Affiliated Fund or other Regulated

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Funds and Affiliated Funds had previously participated in a Co-Investment Transaction with respect to the issuer, then the terms and approval of the Follow-On Investment would be subject to the Standard Review Follow-Ons described in Condition 8. If the Regulated Funds and Affiliated Funds have not previously participated in a Co-Investment Transaction with respect to the issuer but hold a Pre-Boarding Investment, then the terms and approval of the Follow-On Investment would be subject to the Enhanced-Review Follow-Ons described in Condition 9. All Enhanced Review Follow-Ons require the approval of the Required Majority. For a given issuer, the participating Regulated Funds and Affiliated Funds would need to comply with the requirements of Enhanced-Review Follow-Ons only for the first Co-Investment Transaction. Subsequent Co-Investment Transactions with respect to the issuer would be governed by the requirements of Standard Review Follow-Ons.

17. A Regulated Fund would be permitted to invest in Standard Review Follow-Ons either with the approval of the Required Majority under Condition 8(c) or without Board approval under Condition 8(b) if it is (i) a Pro Rata Follow-On Investment [15] or (ii) a Non-Negotiated Follow-On Investment.[16] Applicants believe that these Pro Rata and Non-Negotiated Follow-On Investments do not present a significant opportunity for overreaching on the part of any Adviser and thus do not warrant the time or the attention of the Board. Pro Rata Follow-On Investments and Non-Negotiated Follow-On Investments remain subject to the Board's periodic review in accordance with Condition 10.

C. Dispositions

18. Applicants propose that Dispositions [17] would be divided into two categories. If the Regulated Funds and Affiliated Funds holding investments in the issuer had previously participated in a Co-Investment Transaction with respect to the issuer, then the terms and approval of the Disposition would be subject to the Standard Review Dispositions described in Condition 6. If the Regulated Funds and Affiliated Funds have not previously participated in a Co-Investment Transaction with respect to the issuer but hold a Pre-Boarding Investment, then the terms and approval of the Disposition would be subject to the Enhanced Review Dispositions described in Condition 7. Subsequent Dispositions with respect to the same issuer would be governed by Condition 6 under the Standard Review Dispositions.[18]

19. A Regulated Fund may participate in a Standard Review Disposition either with the approval of the Required Majority under Condition 6(d) or without Board approval under Condition 6(c) if (i) the Disposition is a Pro Rata Disposition [19] or (ii) the securities are Tradable Securities [20] and the Disposition meets the other requirements of Condition 6(c)(ii). Pro Rata Dispositions and Dispositions of a Tradable Security remain subject to the Board's periodic review in accordance with Condition 10.

D. Delayed Settlement

20. Applicants represent that under the terms and Conditions of the application, all Regulated Funds and Affiliated Funds participating in a Co-Investment Transaction will invest at the same time, for the same price and with the same terms, conditions, class, registration rights and any other rights, so that none of them receives terms more favorable than any other. However, the settlement date for an Affiliated Fund in a Co-Investment Transaction may occur up to ten business days after the settlement date for the Regulated Fund, and vice versa.[21] Nevertheless, in all cases, (i) the date on which the commitment of the Affiliated Funds and Regulated Funds is made will be the same even where the settlement date is not and (ii) the earliest settlement date and the latest settlement date of any Affiliated Fund or Regulated Fund participating in the transaction will occur within ten business days of each other.

E. Holders

21. Under Condition 15, if an Adviser, its principals, or any person controlling, controlled by, or under common control with the Adviser or its principals, and the Affiliated Funds (collectively, the ''Holders'') own in the aggregate more than 25 percent of the outstanding

Fund; or (iii) solely with regard to a Regulated Fund that is directly or indirectly wholly-owned by MFC at the time of the transfer, in transactions in which one or more Affiliated Funds transferred assets to the Regulated Fund before the Regulated Fund elected to be regulated as a BDC or registered as an investment company.

[15] A ''Pro Rata Follow-On Investment'' is a Follow-On Investment (i) in which the participation of each Affiliated Fund and each Regulated Fund is proportionate to its outstanding investments in the issuer or security, as appropriate, immediately preceding the Follow-On Investment, and (ii) in the case of a Regulated Fund, a majority of the Board has approved the Regulated Fund's participation in the pro rata Follow-On Investments as being in the best interests of the Regulated Fund. The Regulated Fund's Board may refuse to approve, or at any time rescind, suspend or qualify, its approval of Pro Rata Follow-On Investments, in which case all subsequent Follow-On Investments will be submitted to the Regulated Fund's Eligible Directors in accordance with Condition 8(c).

[16] A ''Non-Negotiated Follow-On Investment'' is a Follow-On Investment in which a Regulated Fund participates together with one or more Affiliated Funds and/or one or more other Regulated Funds (i) in which the only term negotiated by or on behalf of the funds is price and (ii) with respect to which, if the transaction were considered on its own, the funds would be entitled to rely on one of the JT No-Action Letters. ''JT No-Action Letters'' means SMC Capital, Inc., SEC No-Action Letter (pub. avail. Sept. 5, 1995) and Massachusetts Mutual Life Insurance Company, SEC No-Action Letter (pub. avail. June 7, 2000).

[17] ''Disposition'' means the sale, exchange or other disposition of an interest in a security of an issuer.

[18] However, with respect to an issuer, if a Regulated Fund's first Co-Investment Transaction is an Enhanced Review Disposition, and the Regulated Fund does not dispose of its entire position in the Enhanced Review Disposition, then before such Regulated Fund may complete its first Standard Review Follow-On in such issuer, the Eligible Directors must review the proposed Follow-On Investment not only on a stand-alone basis but also in relation to the total economic exposure in such issuer (*i.e.,* in combination with the portion of the Pre-Boarding Investment not disposed of in the Enhanced Review Disposition), and the other terms of the investments. This additional review would be required because such findings would not have been required in connection with the prior Enhanced Review Disposition, but they would have been required had the first Co-Investment Transaction been an Enhanced Review Follow-On.

[19] A ''Pro Rata Disposition'' is a Disposition (i) in which the participation of each Affiliated Fund and each Regulated Fund is proportionate to its outstanding investment in the security subject to Disposition immediately preceding the Disposition; and (ii) in the case of a Regulated Fund, a majority of the Board has approved the Regulated Fund's participation in pro rata Dispositions as being in the best interests of the Regulated Fund. The Regulated Fund's Board may refuse to approve, or at any time rescind, suspend or qualify, its approval of Pro Rata Dispositions, in which case all subsequent Dispositions will be submitted to the Regulated Fund's Eligible Directors.

[20] ''Tradable Security'' means a security that meets the following criteria at the time of Disposition: (i) It trades on a national securities exchange or designated offshore securities market as defined in rule 902(b) under the Securities Act; (ii) it is not subject to restrictive agreements with the issuer or other security holders; and (iii) it trades with sufficient volume and liquidity (findings as to which are documented by the Advisers to any Regulated Funds holding investments in the issuer and retained for the life of the Regulated Fund) to allow each Regulated Fund to dispose of its entire position remaining after the proposed Disposition within a short period of time not exceeding 30 days at approximately the value (as defined by section 2(a)(41) of the Act) at which the Regulated Fund has valued the investment.

[21] Applicants state this may occur for two reasons. First, when the Affiliated Fund or Regulated Fund is not yet fully funded because, when the Affiliated Fund or Regulated Fund desires to make an investment, it must call capital from its investors to obtain the financing to make the investment, and in these instances, the notice requirement to call capital could be as much as ten business days. Second, where, for tax or regulatory reasons, an Affiliated Fund or Regulated Fund does not purchase new issuances immediately upon issuance but only after a short seasoning period of up to ten business days.

voting shares (the ''Shares'') of a Regulated Fund, then the Holders will vote such Shares as directed by an independent third party when voting on matters specified in the Condition; provided however, that Condition 15 will not apply to a Regulated Fund during any time which the Holders in the aggregate own 100% of the Shares of such Regulated Fund. Applicants believe that this Condition will ensure that the Independent Directors will act independently in evaluating Co-Investment Transactions, because the ability of the Adviser or its principals to influence the Independent Directors by a suggestion, explicit or implied, that the Independent Directors can be removed will be limited significantly. The Independent Directors shall evaluate and approve any independent party, taking into account its qualifications, reputation for independence, cost to the shareholders, and other factors that they deem relevant.

Applicants' Legal Analysis

1. Section 17(d) of the Act and rule 17d–1 under the Act prohibit participation by a registered investment company and an affiliated person in any ''joint enterprise or other joint arrangement or profit-sharing plan,'' as defined in the rule, without prior approval by the Commission by order upon application. Section 17(d) of the Act and rule 17d–1 under the Act are applicable to Regulated Funds that are registered closed-end investment companies.

2. Similarly, with regard to BDCs, section 57(a)(4) of the Act generally prohibits certain persons specified in section 57(b) from participating in joint transactions with the BDC or a company controlled by the BDC in contravention of rules as prescribed by the Commission. Section 57(i) of the Act provides that, until the Commission prescribes rules under section 57(a)(4), the Commission's rules under section 17(d) of the Act applicable to registered closed-end investment companies will be deemed to apply to transactions subject to section 57(a)(4). Because the Commission has not adopted any rules under section 57(a)(4), rule 17d–1 also applies to joint transactions with Regulated Funds that are BDCs.

3. Co-Investment Transactions are prohibited by either or both of Rule 17d–1 and Section 57(a)(4) without a prior exemptive order of the Commission to the extent that the Affiliated Funds and the Regulated Funds participating in such transactions fall within the category of persons described by Rule 17d–1 and/or Section 57(b), as applicable, vis-à-vis each participating Regulated Fund. Each of the participating Regulated Funds and Affiliated Funds may be deemed to be affiliated persons vis-à-vis a Regulated Fund within the meaning of section 2(a)(3) by reason of common control because (i) HCIM manages, and may be deemed to control, each of the Existing Affiliated Funds and the MFC Accounts; (ii) HCIM is the investment adviser to, and may be deemed to control the Existing Regulated Funds, and an Adviser will be the investment adviser to, and may be deemed to control, any Future Regulated Fund; and (iii) the Advisers are under common control. Thus, each of the Affiliated Funds could be deemed to be a person related to the Regulated Funds in a manner described by Section 57(b) and related to the other Regulated Funds in a manner described by Rule 17d–1; and therefore the prohibitions of Rule 17d–1 and Section 57(a)(4) would apply respectively to prohibit the Affiliated Funds from participating in Co-Investment Transactions with the Regulated Funds.

4. In passing upon applications under rule 17d–1, the Commission considers whether the company's participation in the joint transaction is consistent with the provisions, policies, and purposes of the Act and the extent to which such participation is on a basis different from or less advantageous than that of other participants.

5. Applicants state that in the absence of the requested relief, in many circumstances the Regulated Funds would be limited in their ability to participate in attractive and appropriate investment opportunities. Applicants state that, as required by Rule 17d–1(b), the Conditions ensure that the terms on which Co-Investment Transactions may be made will be consistent with the participation of the Regulated Funds being on a basis that it is neither different from nor less advantageous than other participants, thus protecting the equity holders of any participant from being disadvantaged. Applicants further state that the Conditions ensure that all Co-Investment Transactions are reasonable and fair to the Regulated Funds and their shareholders and do not involve overreaching by any person concerned, including the Advisers. Applicants state that the Regulated Funds' participation in the Co-Investment Transactions in accordance with the Conditions will be consistent with the provisions, policies, and purposes of the Act and would be done in a manner that is not different from, or less advantageous than, that of other participants.

Applicants' Conditions

Applicants agree that the Order will be subject to the following Conditions:

1. *Identification and Referral of Potential Co-Investment Transactions.*

(a) The Advisers will establish, maintain and implement policies and procedures reasonably designed to ensure that each Adviser is promptly notified of all Potential Co-Investment Transactions that fall within the then-current Objectives and Strategies and Board-Established Criteria of any Regulated Fund the Adviser manages.

(b) When an Adviser to a Regulated Fund is notified of a Potential Co-Investment Transaction under Condition 1(a), the Adviser will make an independent determination of the appropriateness of the investment for the Regulated Fund in light of the Regulated Fund's then-current circumstances.

2. *Board Approvals of Co-Investment Transactions.*

(a) If the Adviser deems a Regulated Fund's participation in any Potential Co-Investment Transaction to be appropriate for the Regulated Fund, it will then determine an appropriate level of investment for the Regulated Fund.

(b) If the aggregate amount recommended by the Advisers to be invested in the Potential Co-Investment Transaction by the participating Regulated Funds and any participating Affiliated Funds, collectively, exceeds the amount of the investment opportunity, the investment opportunity will be allocated among them pro rata based on the size of the Internal Orders, as described in section III.A.1.b. of the application. Each Adviser to a participating Regulated Fund will promptly notify and provide the Eligible Directors with information concerning the Affiliated Funds' and Regulated Funds' order sizes to assist the Eligible Directors with their review of the applicable Regulated Fund's investments for compliance with these Conditions.

(c) After making the determinations required in Condition 1(b) above, each Adviser to a participating Regulated Fund will distribute written information concerning the Potential Co-Investment Transaction (including the amount proposed to be invested by each participating Regulated Fund and each participating Affiliated Fund) to the Eligible Directors of its participating Regulated Fund(s) for their consideration. A Regulated Fund will enter into a Co-Investment Transaction with one or more other Regulated Funds or Affiliated Funds only if, prior to the Regulated Fund's participation in the

Potential Co-Investment Transaction, a Required Majority concludes that:

(i) The terms of the transaction, including the consideration to be paid, are reasonable and fair to the Regulated Fund and its equity holders and do not involve overreaching in respect of the Regulated Fund or its equity holders on the part of any person concerned;

(ii) the transaction is consistent with:

(A) The interests of the Regulated Fund's equity holders; and

(B) the Regulated Fund's then-current Objectives and Strategies;

(iii) the investment by any other Regulated Fund(s) or Affiliated Fund(s) would not disadvantage the Regulated Fund, and participation by the Regulated Fund would not be on a basis different from, or less advantageous than, that of any other Regulated Fund(s) or Affiliated Fund(s) participating in the transaction; provided that the Required Majority shall not be prohibited from reaching the conclusions required by this Condition 2(c)(iii) if:

(A) The settlement date for another Regulated Fund or an Affiliated Fund in a Co-Investment Transaction is later than the settlement date for the Regulated Fund by no more than ten business days or earlier than the settlement date for the Regulated Fund by no more than ten business days, in either case, so long as: (x) The date on which the commitment of the Affiliated Funds and Regulated Funds is made is the same; and (y) the earliest settlement date and the latest settlement date of any Affiliated Fund or Regulated Fund participating in the transaction will occur within ten business days of each other; or

(B) any other Regulated Fund or Affiliated Fund, but not the Regulated Fund itself, gains the right to nominate a director for election to a portfolio company's board of directors, the right to have a board observer or any similar right to participate in the governance or management of the portfolio company so long as: (x) The Eligible Directors will have the right to ratify the selection of such director or board observer, if any; (y) the Adviser agrees to, and does, provide periodic reports to the Regulated Fund's Board with respect to the actions of such director or the information received by such board observer or obtained through the exercise of any similar right to participate in the governance or management of the portfolio company; and (z) any fees or other compensation that any other Regulated Fund or Affiliated Fund or any affiliated person of any other Regulated Fund or Affiliated Fund receives in connection with the right of one or more Regulated Funds or Affiliated Funds to nominate a director or appoint a board observer or otherwise to participate in the governance or management of the portfolio company will be shared proportionately among any participating Affiliated Funds (who may, in turn, share their portion with their affiliated persons) and any participating Regulated Fund(s) in accordance with the amount of each such party's investment; and

(iv) the proposed investment by the Regulated Fund will not involve compensation, remuneration or a direct or indirect [22] financial benefit to the Advisers, any other Regulated Fund, the Affiliated Funds or any affiliated person of any of them (other than the parties to the Co-Investment Transaction), except (A) to the extent permitted by Condition 14, (B) to the extent permitted by Section 17(e) or 57(k), as applicable, (C) indirectly, as a result of an interest in the securities issued by one of the parties to the Co-Investment Transaction, or (D) in the case of fees or other compensation described in Condition 2(c)(iii)(B)(z).

3. *Right to Decline.* Each Regulated Fund has the right to decline to participate in any Potential Co-Investment Transaction or to invest less than the amount proposed.

4. *General Limitation.* Except for Follow-On Investments made in accordance with Conditions 8 and 9 below,[23] a Regulated Fund will not invest in reliance on the Order in any issuer in which a Related Party has an investment.[24]

5. *Same Terms and Conditions.* A Regulated Fund will not participate in any Potential Co-Investment Transaction unless (i) the terms, conditions, price, class of securities to be purchased, date on which the commitment is entered into and registration rights (if any) will be the same for each participating Regulated Fund and Affiliated Fund and (ii) the earliest settlement date and the latest settlement date of any participating Regulated Fund or Affiliated Fund will occur as close in time as practicable and in no event more than ten business days apart. The grant to one or more Regulated Funds or Affiliated Funds, but not the respective Regulated Fund, of the right to nominate a director for election to a portfolio company's board of directors, the right to have an observer on the board of directors or similar rights to participate in the governance or management of the portfolio company will not be interpreted so as to violate this Condition 5, if Condition 2(c)(iii)(B) is met.

6. *Standard Review Dispositions.*

(a) *General.* If any Regulated Fund or Affiliated Fund elects to sell, exchange or otherwise dispose of an interest in a security and one or more Regulated Funds and Affiliated Funds have previously participated in a Co-Investment Transaction with respect to the issuer, then:

(i) the Adviser to such Regulated Fund or Affiliated Fund will notify each Regulated Fund that holds an investment in the issuer of the proposed Disposition at the earliest practical time; and

(ii) the Adviser to each Regulated Fund that holds an investment in the issuer will formulate a recommendation as to participation by such Regulated Fund in the Disposition.

(b) *Same Terms and Conditions.* Each Regulated Fund will have the right to participate in such Disposition on a proportionate basis, at the same price and on the same terms and conditions as those applicable to the Affiliated Funds and any other Regulated Fund.

(c) *No Board Approval Required.* A Regulated Fund may participate in such a Disposition without obtaining prior approval of the Required Majority if:

(i) (A) the participation of each Regulated Fund and Affiliated Fund in such Disposition is proportionate to its then-current holding of the security (or securities) of the issuer that is (or are) the subject of the Disposition;[25] (B) the Board of the Regulated Fund has approved as being in the best interests of the Regulated Fund the ability to

[22] For example, procuring the Regulated Fund's investment in a Potential Co-Investment Transaction to permit an affiliate to complete or obtain better terms in a separate transaction would constitute an indirect financial benefit.

[23] This exception applies only to Follow-On Investments by a Regulated Fund in issuers in which that Regulated Fund already holds investments.

[24] ''Related Party'' means (i) any Close Affiliate and (ii) in respect of matters as to which any Adviser has knowledge, any Remote Affiliate. ''Close Affiliate'' means the Advisers, the Regulated Funds, the Affiliated Funds and any other person described in Section 57(b) (after giving effect to Rule 57b–1) in respect of any Regulated Fund (treating any registered investment company or series thereof as a BDC for this purpose) except for limited partners included solely by reason of the reference in Section 57(b) to Section 2(a)(3)(D). ''Remote Affiliate'' means any person described in Section 57(e) in respect of any Regulated Fund (treating any registered investment company or series thereof as a BDC for this purpose) and any limited partner holding 5% or more of the relevant limited partner interests that would be a Close Affiliate but for the exclusion in that definition.

[25] In the case of any Disposition, proportionality will be measured by each participating Regulated Fund's and Affiliated Fund's outstanding investment in the security in question immediately preceding the Disposition.

participate in such Dispositions on a pro rata basis (as described in greater detail in the application); and (C) the Board of the Regulated Fund is provided on a quarterly basis with a list of all Dispositions made in accordance with this Condition; or

(ii) each security is a Tradable Security and (A) the Disposition is not to the issuer or any affiliated person of the issuer; and (B) the security is sold for cash in a transaction in which the only term negotiated by or on behalf of the participating Regulated Funds and Affiliated Funds is price.

(d) *Standard Board Approval.* In all other cases, the Adviser will provide its written recommendation as to the Regulated Fund's participation to the Eligible Directors and the Regulated Fund will participate in such Disposition solely to the extent that a Required Majority determines that it is in the Regulated Fund's best interests.

7. *Enhanced Review Dispositions.*

(a) *General.* If any Regulated Fund or Affiliated Fund elects to sell, exchange or otherwise dispose of a Pre-Boarding Investment in a Potential Co-Investment Transaction and the Regulated Funds and Affiliated Funds have not previously participated in a Co-Investment Transaction with respect to the issuer:

(i) The Adviser to such Regulated Fund or Affiliated Fund will notify each Regulated Fund that holds an investment in the issuer of the proposed Disposition at the earliest practical time;

(ii) the Adviser to each Regulated Fund that holds an investment in the issuer will formulate a recommendation as to participation by such Regulated Fund in the Disposition; and

(iii) the Advisers will provide to the Board of each Regulated Fund that holds an investment in the issuer all information relating to the existing investments in the issuer of the Regulated Funds and Affiliated Funds, including the terms of such investments and how they were made, that is necessary for the Required Majority to make the findings required by this Condition.

(b) *Enhanced Board Approval.* The Adviser will provide its written recommendation as to the Regulated Fund's participation to the Eligible Directors, and the Regulated Fund will participate in such Disposition solely to the extent that a Required Majority determines that:

(i) The Disposition complies with Conditions 2(c)(i), (ii), (iii)(A), and (iv); and

(ii) the making and holding of the Pre-Boarding Investments were not prohibited by Section 57 or Rule 17d–1, as applicable, and records the basis for the finding in the Board minutes.

(c) *Additional Requirements.* The Disposition may only be completed in reliance on the Order if:

(i) *Same Terms and Conditions.* Each Regulated Fund has the right to participate in such Disposition on a proportionate basis, at the same price and on the same terms and conditions as those applicable to the Affiliated Funds and any other Regulated Fund;

(ii) *Original Investments.* All of the Affiliated Funds' and Regulated Funds' investments in the issuer are Pre-Boarding Investments;

(iii) *Advice of counsel.* Independent counsel to the Board advises that the making and holding of the investments in the Pre-Boarding Investments were not prohibited by Section 57 (as modified by Rule 57b–1) or Rule 17d–1, as applicable;

(iv) *Multiple Classes of Securities.* All Regulated Funds and Affiliated Funds that hold Pre-Boarding Investments in the issuer immediately before the time of completion of the Co-Investment Transaction hold the same security or securities of the issuer. For the purpose of determining whether the Regulated Funds and Affiliated Funds hold the same security or securities, they may disregard any security held by some but not all of them if, prior to relying on the Order, the Required Majority is presented with all information necessary to make a finding, and finds, that: (x) Any Regulated Fund's or Affiliated Fund's holding of a different class of securities (including for this purpose a security with a different maturity date) is immaterial [26] in amount, including immaterial relative to the size of the issuer; and (y) the Board records the basis for any such finding in its minutes. In addition, securities that differ only in respect of issuance date, currency, or denominations may be treated as the same security; and

(v) *No control.* The Affiliated Funds, the other Regulated Funds and their affiliated persons (within the meaning of Section 2(a)(3)(C) of the Act), individually or in the aggregate, do not control the issuer of the securities (within the meaning of Section 2(a)(9) of the Act).

8. *Standard Review Follow-Ons.*

(a) *General.* If any Regulated Fund or Affiliated Fund desires to make a Follow-On Investment in an issuer and the Regulated Funds and Affiliated Funds holding investments in the issuer previously participated in a Co-Investment Transaction with respect to the issuer:

(i) The Adviser to each such Regulated Fund or Affiliated Fund will notify each Regulated Fund that holds securities of the portfolio company of the proposed transaction at the earliest practical time; and

(ii) the Adviser to each Regulated Fund that holds an investment in the issuer will formulate a recommendation as to the proposed participation, including the amount of the proposed investment, by such Regulated Fund.

(b) *No Board Approval Required.* A Regulated Fund may participate in the Follow-On Investment without obtaining prior approval of the Required Majority if:

(i)(A) the proposed participation of each Regulated Fund and each Affiliated Fund in such investment is proportionate to its outstanding investments in the issuer or the security at issue, as appropriate,[27] immediately preceding the Follow-On Investment; and (B) the Board of the Regulated Fund has approved as being in the best interests of the Regulated Fund the ability to participate in Follow-On Investments on a pro rata basis (as described in greater detail in the application); or

(ii) it is a Non-Negotiated Follow-On Investment.

(c) *Standard Board Approval.* In all other cases, the Adviser will provide its written recommendation as to the Regulated Fund's participation to the Eligible Directors and the Regulated Fund will participate in such Follow-On Investment solely to the extent that a Required Majority makes the determinations set forth in Condition 2(c). If the only previous Co-Investment Transaction with respect to the issuer was an Enhanced Review Disposition the Eligible Directors must complete this review of the proposed Follow-On

[26] In determining whether a holding is ''immaterial'' for purposes of the Order, the Required Majority will consider whether the nature and extent of the interest in the transaction or arrangement is sufficiently small that a reasonable person would not believe that the interest affected the determination of whether to enter into the transaction or arrangement or the terms of the transaction or arrangement.

[27] To the extent that a Follow-On Investment opportunity is in a security or arises in respect of a security held by the participating Regulated Funds and Affiliated Funds, proportionality will be measured by each participating Regulated Fund's and Affiliated Fund's outstanding investment in the security in question immediately preceding the Follow-On Investment using the most recent available valuation thereof. To the extent that a Follow-On Investment opportunity relates to an opportunity to invest in a security that is not in respect of any security held by any of the participating Regulated Funds or Affiliated Funds, proportionality will be measured by each participating Regulated Fund's and Affiliated Fund's outstanding investment in the issuer immediately preceding the Follow-On Investment using the most recent available valuation thereof.

Investment both on a stand-alone basis and together with the Pre-Boarding Investments in relation to the total economic exposure and other terms of the investment.

(d) *Allocation.* If, with respect to any such Follow-On Investment:

(i) The amount of the opportunity proposed to be made available to any Regulated Fund is not based on the Regulated Funds' and the Affiliated Funds' outstanding investments in the issuer or the security at issue, as appropriate, immediately preceding the Follow-On Investment; and

(ii) the aggregate amount recommended by the Advisers to be invested in the Follow-On Investment by the participating Regulated Funds and any participating Affiliated Funds, collectively, exceeds the amount of the investment opportunity, then the Follow-On Investment opportunity will be allocated among them *pro rata* based on the size of the Internal Orders, as described in section III.A.1.b. of the application.

(e) *Other Conditions.* The acquisition of Follow-On Investments as permitted by this Condition will be considered a Co-Investment Transaction for all purposes and subject to the other Conditions set forth in the application.

9. *Enhanced Review Follow-Ons.*

(a) *General.* If any Regulated Fund or Affiliated Fund desires to make a Follow-On Investment in an issuer that is a Potential Co-Investment Transaction and the Regulated Funds and Affiliated Funds holding investments in the issuer have not previously participated in a Co-Investment Transaction with respect to the issuer:

(i) The Adviser to each such Regulated Fund or Affiliated Fund will notify each Regulated Fund that holds securities of the portfolio company of the proposed transaction at the earliest practical time;

(ii) the Adviser to each Regulated Fund that holds an investment in the issuer will formulate a recommendation as to the proposed participation, including the amount of the proposed investment, by such Regulated Fund; and

(iii) the Advisers will provide to the Board of each Regulated Fund that holds an investment in the issuer all information relating to the existing investments in the issuer of the Regulated Funds and Affiliated Funds, including the terms of such investments and how they were made, that is necessary for the Required Majority to make the findings required by this Condition.

(b) *Enhanced Board Approval.* The Adviser will provide its written recommendation as to the Regulated Fund's participation to the Eligible Directors, and the Regulated Fund will participate in such Follow-On Investment solely to the extent that a Required Majority reviews the proposed Follow-On Investment both on a stand-alone basis and together with the Pre-Boarding Investments in relation to the total economic exposure and other terms and makes the determinations set forth in Condition 2(c). In addition, the Follow-On Investment may only be completed in reliance on the Order if the Required Majority of each participating Regulated Fund determines that the making and holding of the Pre-Boarding Investments were not prohibited by Section 57 (as modified by Rule 57b–1) or Rule 17d–1, as applicable. The basis for the Board's findings will be recorded in its minutes.

(c) *Additional Requirements.* The Follow-On Investment may only be completed in reliance on the Order if:

(i) *Original Investments.* All of the Affiliated Funds' and Regulated Funds' investments in the issuer are Pre-Boarding Investments;

(ii) *Advice of counsel.* Independent counsel to the Board advises that the making and holding of the investments in the Pre-Boarding Investments were not prohibited by Section 57 (as modified by Rule 57b–1) or Rule 17d–1, as applicable;

(iii) *Multiple Classes of Securities.* All Regulated Funds and Affiliated Funds that hold Pre-Boarding Investments in the issuer immediately before the time of completion of the Co-Investment Transaction hold the same security or securities of the issuer. For the purpose of determining whether the Regulated Funds and Affiliated Funds hold the same security or securities, they may disregard any security held by some but not all of them if, prior to relying on the Order, the Required Majority is presented with all information necessary to make a finding, and finds, that: (x) Any Regulated Fund's or Affiliated Fund's holding of a different class of securities (including for this purpose a security with a different maturity date) is immaterial in amount, including immaterial relative to the size of the issuer; and (y) the Board records the basis for any such finding in its minutes. In addition, securities that differ only in respect of issuance date, currency, or denominations may be treated as the same security; and

(iv) *No control.* The Affiliated Funds, the other Regulated Funds and their affiliated persons (within the meaning of Section 2(a)(3)(C) of the Act), individually or in the aggregate, do not control the issuer of the securities (within the meaning of Section 2(a)(9) of the Act).

(d) *Allocation.* If, with respect to any such Follow-On Investment:

(i) The amount of the opportunity proposed to be made available to any Regulated Fund is not based on the Regulated Funds' and the Affiliated Funds' outstanding investments in the issuer or the security at issue, as appropriate, immediately preceding the Follow-On Investment; and.

(ii) the aggregate amount recommended by the Advisers to be invested in the Follow-On Investment by the participating Regulated Funds and any participating Affiliated Funds, collectively, exceeds the amount of the investment opportunity, then the Follow-On Investment opportunity will be allocated among them pro rata based on the size of the Internal Orders, as described in section III.A.1.(b) of the application.

(e) *Other Conditions.* The acquisition of Follow-On Investments as permitted by this Condition will be considered a Co-Investment Transaction for all purposes and subject to the other Conditions set forth in the application.

10. *Board Reporting, Compliance and Annual Re-Approval.*

(a) Each Adviser to a Regulated Fund will present to the Board of each Regulated Fund, on a quarterly basis, and at such other times as the Board may request, (i) a record of all investments in Potential Co-Investment Transactions made by any of the other Regulated Funds or any of the Affiliated Funds during the preceding quarter that fell within the Regulated Fund's then-current Objectives and Strategies and Board-Established Criteria that were not made available to the Regulated Fund, and an explanation of why such investment opportunities were not made available to the Regulated Fund; (ii) a record of all Follow-On Investments in and Dispositions of investments in any issuer in which the Regulated Fund holds any investments by any Affiliated Fund or other Regulated Fund during the prior quarter; and (iii) all information concerning Potential Co-Investment Transactions and Co-Investment Transactions, including investments made by other Regulated Funds or Affiliated Funds that the Regulated Fund considered but declined to participate in, so that the Independent Directors, may determine whether all Potential Co-Investment Transactions and Co-Investment Transactions during the preceding quarter, including those investments that the Regulated Fund considered but

declined to participate in, comply with the Conditions.

(b) All information presented to the Regulated Fund's Board pursuant to this Condition will be kept for the life of the Regulated Fund and at least two years thereafter, and will be subject to examination by the Commission and its staff.

(c) Each Regulated Fund's chief compliance officer, as defined in rule 38a-1(a)(4), will prepare an annual report for its Board each year that evaluates (and documents the basis of that evaluation) the Regulated Fund's compliance with the terms and Conditions of the application and the procedures established to achieve such compliance.

(d) The Independent Directors will consider at least annually whether continued participation in new and existing Co-Investment Transactions is in the Regulated Fund's best interests.

11. *Record Keeping.* Each Regulated Fund will maintain the records required by Section 57(f)(3) of the Act as if each of the Regulated Funds were a BDC and each of the investments permitted under these Conditions were approved by the Required Majority under Section 57(f).

12. *Director Independence.* No Independent Director of a Regulated Fund will also be a director, general partner, managing member or principal, or otherwise be an ''affiliated person'' (as defined in the Act) of any Affiliated Fund.

13. *Expenses.* The expenses, if any, associated with acquiring, holding or disposing of any securities acquired in a Co-Investment Transaction (including, without limitation, the expenses of the distribution of any such securities registered for sale under the Securities Act) will, to the extent not payable by the Advisers under their respective advisory agreements with the Regulated Funds and the Affiliated Funds, be shared by the Regulated Funds and the participating Affiliated Funds in proportion to the relative amounts of the securities held or being acquired or disposed of, as the case may be.

14. *Transaction Fees.*[28] Any transaction fee (including break-up, structuring, monitoring or commitment fees but excluding brokerage or underwriting compensation permitted by Section 17(e) or 57(k)) received in connection with any Co-Investment Transaction will be distributed to the participants on a pro rata basis based on the amounts they invested or committed, as the case may be, in such Co-Investment Transaction. If any transaction fee is to be held by an Adviser pending consummation of the transaction, the fee will be deposited into an account maintained by the Adviser at a bank or banks having the qualifications prescribed in Section 26(a)(1), and the account will earn a competitive rate of interest that will also be divided pro rata among the participants. None of the Advisers, the Affiliated Funds, the other Regulated Funds or any affiliated person of the Affiliated Funds or the Regulated Funds will receive any additional compensation or remuneration of any kind as a result of or in connection with a Co-Investment Transaction other than (i) in the case of the Regulated Funds and the Affiliated Funds, the pro rata transaction fees described above and fees or other compensation described in Condition 2(c)(iii)(B)(z), (ii) brokerage or underwriting compensation permitted by Section 17(e) or 57(k) or (iii) in the case of the Advisers, investment advisory compensation paid in accordance with investment advisory agreements between the applicable Regulated Fund(s) or Affiliated Fund(s) and its Adviser.

15. *Independence.* If the Holders own in the aggregate more than 25 percent of the Shares of a Regulated Fund, then the Holders will vote such Shares as directed by an independent third party when voting on (1) the election of directors; (2) the removal of one or more directors; or (3) any other matter under either the Act or applicable State law affecting the Board's composition, size or manner of election; provided however, that this Condition 15 will not apply to a Regulated Fund during any time which the Holders in the aggregate own 100% of the Shares of such Regulated Fund.

For the Commission, by the Division of Investment Management, under delegated authority.

Eduardo A. Aleman,

Deputy Secretary.

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[28] Applicants are not requesting and the Commission is not providing any relief for transaction fees received in connection with any Co-Investment Transaction.

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:

Rule 15b1–1/Form BD, SEC File No. 270–19, OMB Control No. 3235–0012

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the collection of information provided for in Rule 15b1–1 (17 CFR 240.15b1–1) and Form BD (17 CFR 249.501) under the Securities Exchange Act of 1934 (17 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Form BD is the application form used by firms to apply to the Commission for registration as a broker-dealer, as required by Rule 15b1–1. Form BD also is used by firms other than banks and registered broker-dealers to apply to the Commission for registration as a municipal securities dealer or a government securities broker-dealer. In addition, Form BD is used to change information contained in a previous Form BD filing that becomes inaccurate.

The total industry-wide annual time burden imposed by Form BD is approximately 4,118.07 hours, based on approximately 11,137 responses (183 initial filings + 10,954 amendments). Each application filed on Form BD requires approximately 2.75 hours to complete and each amended Form BD requires approximately 20 minutes to complete. (183×2.75 hours = 503.25 hours; $10{,}954 \times 0.33$ hours = 3,614.82 hours; 503.25 hours + 3,614.82 hours = 4,118.07 hours.) The staff believes that a broker-dealer would have a Compliance Manager complete and file both applications and amendments on Form BD at a cost of $314/hour. Consequently, the staff estimates that the total internal cost of compliance associated with the annual time burden is approximately $1,293,073.98 per year ($314 × 4,118.07). There is no external cost burden associated with Rule 15b1–1 and Form BD.

The Commission uses the information disclosed by applicants in Form BD: (1) To determine whether the applicant meets the standards for registration set forth in the provisions of the Exchange Act; (2) to develop a central information resource where members of the public may obtain relevant, up-to-date information about broker-dealers, municipal securities dealers, and government securities broker-dealers, and where the Commission, other regulators, and SROs may obtain information for investigatory purposes in connection with securities litigation; and (3) to develop statistical

information about broker-dealers, municipal securities dealers, and government securities broker-dealers. Without the information disclosed in Form BD, the Commission could not effectively implement policy objectives of the Exchange Act with respect to its investor protection function.

Completing and filing Form BD is mandatory in order to engage in broker-dealer activity. Compliance with Rule 15b1–1 does not involve the collection of confidential information.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: Charles Riddle, Acting Director/Chief Information Officer, Securities and Exchange Commission, c/o Candace Kenner, 100 F Street NE, Washington, DC 20549, or send an email to *PRA_Mailbox@sec.gov*.

Dated: May 28, 2019.

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–11432 Filed 5–31–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85945; File No. SR–NYSE–2019–29]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend NYSE Rules 7.6, 7.31, 7.34, 98, 107B and 131A, To Specify Order Behavior for Orders Entered Via the Pillar Phase II Protocols

May 28, 2019.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that on May 15, 2019, New York Stock Exchange LLC (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the 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 Rules 7.6, 7.31, 7.34, 98, 107B and 131A to specify order behavior for orders entered via the Pillar phase II protocols. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rules 7.6 (Trading Differentials), 7.31 (Orders and Modifiers), 7.34 (Trading Sessions), 98 (Operation of a DMM Unit), 107B (Supplemental Liquidity Providers) and 131A (A Member Organization Shall Use Its Own Mnemonic When Entering Orders) to specify order behavior for orders entered via the Pillar phase II protocols.

Background

Currently, the Exchange trades UTP Securities on its Pillar trading platform, subject to Pillar Platform Rules 1P–13P.[4] In the next phase of Pillar, the Exchange proposes to transition trading of Exchange-listed securities to the Pillar trading platform.[5] Once transitioned to Pillar, such securities will also be subject to the Pillar Platform Rules 1P–13P.

Member organizations enter orders and order instructions by using communication protocols that map to the order types and modifiers described in Exchange rules. Currently, all member organizations communicate with the Exchange using Pillar phase I protocols, which support trading both under the Pillar Platform Rules and in Exchange-listed securities. In anticipation of the transition of NYSE-listed securities to Pillar, the Exchange is introducing new technology to support how member organizations communicate with the Exchange when trading on the Pillar trading platform (''Pillar phase II protocols''). Because Pillar phase II protocols will support new order functionality, the Exchange proposes to revise its rules to reflect these changes.

During this implementation, there will be a period when both the Pillar phase I and Pillar phase II protocols will be available to member organizations other than designated market makers (''DMM'').[6] Accordingly, the Exchange

[4] ''UTP Security'' is defined as a security that is listed on a national securities exchange other than the Exchange and that trades on the Exchange pursuant to unlisted trading privileges. *See* Rule 1.1.

[5] The Exchange has announced that, subject to rule approvals, the Exchange will begin transitioning Exchange-listed securities to Pillar on July 15, 2019, available here: *https://www.nyse.com/publicdocs/nyse/markets/nyse/NYSE_Pillar_Update_NGW.pdf.* The Exchange will publish by separate Trader Update a complete symbol migration schedule.

[6] The Exchange's affiliate, NYSE Arca, Inc. (''NYSE Arca''), similarly offered a parallel period when both Pillar phase I and Pillar phase II

proposes to amend its rules to describe how a member organization's orders would behave depending on the protocol a member organization chooses to use. Once Exchange-listed securities transition to Pillar, DMMs will be required to connect to the Exchange using Pillar phase II protocols for trading in their assigned securities.

Proposed Amendment to Rule 7.6

Rule 7.6 sets forth the Exchange's Trading Differentials, also referred to as the minimum price variation (''MPV'') for quoting and entry of securities traded on the Exchange. The rule currently provides that the MPV for quoting and entry of orders in securities traded on the Exchange is $0.01, with the exception of securities that are priced less than $1.00 for which the MPV for quoting and entry or orders is $0.0001. On the Pillar trading platform, when using Pillar phase I protocols, orders with a limit price of less than $1.00 in securities that trade in prices of $100,000 or above, must be entered in no more than two decimal places, *e.g.,* $0.01, and when using Pillar phase II protocols, such orders must be entered in no more than three decimal places, *e.g.,* $0.001. The Exchange notes that this functionality is only applicable to one security traded on the Exchange. The Exchange proposes to codify this functionality in proposed Commentary .01 to Rule 7.6. As proposed, Commentary .01 to Rule 7.6 would provide that on Pillar, when using Pillar phase I protocols, the MPV for orders with a limit price of less than $1.00 in securities that trade in prices of $100,000 or above is $0.01, and when using Pillar phase II protocols, the MPV for such orders is $0.001.

Proposed Amendment to Rule 7.31

The Exchange proposes to amend Rule 7.31 to reflect that under the Pillar phase II protocols, the Exchange would use a member organization's MPID, rather than a Client ID, to assess whether to apply Self-Trade Prevention Modifiers (''STP'') against two matching orders. To reflect this change, the Exchange proposes to add new subsection (D) to Rule 7.31(i)(2) that would provide that for purposes of STP, references to Client ID mean a Client ID when using Pillar phase I protocols to communicate with the Exchange or an MPID when using Pillar phase II protocols to communicate with the Exchange. This proposed rule change is based in part on the rules of the Exchange's affiliated exchanges, NYSE Arca, NYSE American LLC (''NYSE American''), and NYSE National, Inc. (''NYSE National''), which also require the use of an MPID for their respective rules relating to STP.[7]

Proposed Amendment to Rule 7.34

The Exchange proposes to amend Rule 7.34 to reflect that under the Pillar phase II protocols, the Exchange would reject orders that do not include a designation for which trading session(s) the order will remain in effect. Current Rule 7.34(b)(1) provides that any order entered before or during the Early or Core Trading Session will be deemed designated for the Early Trading Session and the Core Trading Session. Further, current Rule 7.34(b)(2) provides that an order without a time-in-force designation will be deemed designated with a day time-in-force modifier.

The Exchange proposes that when member organizations use Pillar phase II protocols to enter an order, the Exchange would reject any order that does not include a trading session designation. To reflect this functionality, the Exchange proposes to add the following sentence to Rule 7.34(b)(1): ''For member organizations that communicate with the Exchange using Pillar phase II protocols, orders entered without a trading session will be rejected.'' This proposed rule text is based on the rules of the Exchange's affiliates that use Pillar phase II protocols, and which also reject orders that do not include a trading session designation.[8] To specify that the current rule processing is available only for orders entered via the Pillar phase I protocols, the Exchange proposes to add the following introductory text to Rule 7.34(b)(2): ''For member organizations that communicate with the Exchange using Pillar phase I protocols.''

Proposed Amendment to Rule 98

Rule 98(c) sets forth specified restrictions to operating a DMM unit.[9] Among other requirements, Rule 98(c)(4) provides that any proprietary interest entered into Exchange systems by a DMM unit in DMM Securities[10] must be identifiable as DMM unit interest, unless such proprietary interest is for the purposes of facilitating the execution of an order received from a customer (whether the DMM's own customer or the customer of another broker-dealer) and is on a riskless principal basis, or on a principal basis to provide price improvement to the customer. The Exchange does not specify which system(s) a DMM unit must use because, as the Exchange's trading systems continue to evolve, the manner by which interest would be identified as DMM interest could change. However, Rule 98(c)(4) requires that a DMM use a unique mnemonic that identifies to the Exchange its customer-driven orders in DMM securities and that such mnemonic may not be used for trading activity on the Exchange in DMM securities that are not customer-driven orders. Because mnemonics will not be supported on Pillar phase II protocols, the Exchange will instead require DMMs to use a unique identifier that is not a mnemonic to identify its customer-driven orders in DMM securities. The Exchange proposes to amend Rule 98(c)(4) to reflect this change by replacing the term ''mnemonic'' in Rule 98(c)(4) with the term ''identifier.''

Proposed Amendment to Rule 107B

Rule 107B provides for a class of market participants referred to as Supplemental Liquidity Providers or ''SLPs.'' Approved Exchange member organizations are eligible to be an SLP. SLPs supplement the liquidity provided by DMMs. SLPs have monthly quoting requirements that may qualify them to receive SLP rebates. Rule 107B requires that an SLP use a unique mnemonic that identify the SLP trading activity of each SLP in assigned SLP securities.[11] Because all order flow in an assigned SLP security using that mnemonic is treated as SLP volume, a member organization may not use such identified mnemonics for trading activity at the Exchange in assigned SLP securities that is not SLP trading activity. However, to enable the member organization to use the same mnemonic for both SLP and non-SLP trading activity in different securities, an SLP may use mnemonics used for SLP trading for trading activity in securities not assigned to the SLP. Additionally,

protocols were available to ETP Holders. *See* Securities Exchange Act Release No. 79588 (December 23, 2016), 81 FR 96534 (December 30, 2016) (SR–NYSEArca-2016–170) (Notice of filing and immediate effectiveness of proposed rule change).

[7] *See* NYSE Arca Rule 7.31–E(i)(2), NYSE American Rule 7.31E(i)(2), and NYSE National Rule 7.31(i)(2).

[8] *See* NYSE Arca Rule 7.34–E(b)(1), NYSE American Rule 7.34E(b)(1), and NYSE National Rule 7.34(b)(1).

[9] For purposes of Rule 98, the term ''DMM unit'' means a trading unit within a member organization that is approved pursuant to Rule 103 to act as a DMM unit. *See* Rule 98(b)(1). The term ''Designated Market Maker'' means an individual member, officer, partner, employee or associated person of a Designated Market Maker who is approved by the Exchange to act in the capacity of a DMM. *See* Rule 2(i).

[10] The term ''DMM securities'' means any securities allocated to the DMM unit pursuant to Rule 103B or other applicable rules. *See* Rule 98(b)(2).

[11] *See* Rule 107B(c)(2).

the rule specifies that if a member organization does not identify such mnemonics to the Exchange, the member organization would not receive credit for such SLP trading.

The Exchange proposes to amend Rule 107B to provide that SLPs may continue to use mnemonics when communicating with the Exchange using Pillar phase I protocols, but that if an SLP uses Pillar Phase II protocols, it would be required to use MMID in lieu of a mnemonic. The Exchange proposes to adopt this distinction in current Rules 107B(c)(2), 107B(d)(3), and 107B(g)(2). This proposed rule change would not alter any of the substantive requirements of Rule 107B and instead would reflect the new communication protocol to comply with the existing rule requirements.

Proposed Amendment to Rule 131A

The Exchange proposes to amend Rule 131A, which set forth the requirements relating to mnemonics, to reflect that the rule would not be applicable to trading on the Pillar platform. Specifically, since the Exchange would use MPIDs under Pillar phase II protocols and would not use mnemonics, the Exchange proposes to adopt the following preamble to the current rule: This rule is not applicable to member organizations using Pillar phase II protocols to communicate with the Exchange.

* * * * *

Because of the technology changes associated with this proposed rule change, the Exchange will announce the implementation date by Trader Update. The Exchange anticipates implementing these changes in the second quarter, before the Exchange begins the transition of Exchange-listed securities to Pillar.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[12] in general, and furthers the objectives of Section 6(b)(5),[13] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed change to Rule 7.6 to reject orders with a limit price of less than $1.00 in securities that trade in prices of $100,000 or above if not entered with an MPV of $0.01 when using Pillar phase I protocols, and to reject such orders if not entered with an MPV of $0.001 when using Pillar phase II protocols, would remove impediments to and perfect the mechanism of a free and open market and a national market system because it provides transparency of the circumstances when orders would be rejected depending on the communication protocol used by the member organization and the MPV in which they are entered.

The Exchange believes that the proposed change to Rule 7.31 to specify that a member organization's MPID rather than Client ID would be used for STP purposes when a member organization uses Pillar phase II protocols would remove impediments to and perfect the mechanism of a free and open market and a national market system by providing notice to member organizations of which orders would be matched for purposes of STP, depending on the communication protocol that they use.

The Exchange believes that the proposed change to Rule 7.34 to reject orders that do not include a trading session designation would remove impediments to and perfect the mechanism of a free and open market and a national market system because it provides transparency and uniformity of the circumstances when an order would be rejected depending on the communication protocol used by the member organization.

The Exchange believes that the proposed change to Rule 98 would remove impediments to and perfect the mechanism of a free and open market by providing greater specificity in Rule 98 regarding the manner by which DMMs would be required to send customer-driven orders in DMM securities.

The Exchange further believes that amending Rule 107B to specify whether a mnemonic or MMID should be used, depending on communication protocol, would remove impediments to and perfect the mechanism of a free and open market and a national market system by providing transparency to SLPs of how they must comply with the requirements of Rule 107B when using Pillar phase II protocols.

Finally, the Exchange believes that it would remove impediments to and perfect the mechanism of a free and open market and a national market system to specify which current rules would not be applicable to trading on the Pillar trading platform. The Exchange believes that adding a legend which clearly states that a rule would not be applicable to trading on the Pillar trading platform would promote transparency regarding which rules would govern trading on the Exchange once it transitions to Pillar.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes the proposed rule change to reject orders in high priced securities depending on the communication protocol used by the member organization and the MPV in which they are entered would not impose any burden on competition because the proposed change is not designed to address any competitive issues, but rather, would promote transparency in the Exchange's rules. The Exchange believes that the proposed rule change to specify that a member organization's MPID rather than Client ID would be used for STP purposes when a member organization uses Pillar phase II protocols is not designed to address any competitive issues, but rather, would provide clarity regarding when the STP functionality would be available to a member organization, depending on the communication protocol that they use. Additionally, the Exchange believes that the proposed rule change to reject orders if they do not include a trading session designation would not impose any burden on competition because the proposed change is not designed to address any competitive issues, but rather, would promote transparency and uniformity by specifying when an order would be rejected depending on the communication protocol used by a member organization. Finally, the Exchange believes that amending Exchange rules to specify how orders must be identified depending on which Pillar protocol is used to communicate with the Exchange is intended to provide transparency regarding how orders would be processed depending on the communication protocol used by a member organization.

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(5).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [14] and Rule 19b–4(f)(6) thereunder.[15] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [16] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSE–2019–29 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–NYSE–2019–29. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2019–29 and should be submitted on or before June 24, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–11445 Filed 5–31–19; 8:45 am]

BILLING CODE 8011–01–P

[14] 15 U.S.C. 78s(b)(3)(A)(iii).

[15] 17 CFR 240.19b–4(f)(6).

[16] 15 U.S.C. 78s(b)(2)(B).

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85946; File No. SR–NYSEArca–2019–04]

Self-Regulatory Organizations; NYSE Arca, Inc.; Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To Amend NYSE Arca Rule 5.2–E(j)(3) and To Adopt Generic Listing Standards for Investment Company Units Based on an Index or Portfolio of Municipal Securities

May 28, 2019.

I. Introduction

On February 8, 2019, NYSE Arca, Inc. (''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to adopt generic listing standards for Investment Company Units (''Units'') based on an index or portfolio of municipal securities. The proposed rule change was published for comment in the **Federal Register** on February 27, 2019.[3] On April 9, 2019, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to approve or disapprove the proposed rule change.[5] The Commission has received no comments on the proposal. The Commission is publishing this order to institute proceedings pursuant to Section 19(b)(2)(B) of the Act [6] to determine whether to approve or disapprove the proposed rule change.

II. Summary of the Proposed Rule Change [7]

NYSE Arca Rule 5.2–E(j)(3) permits the Exchange to list a series of Units based on an index or portfolio of underlying securities. Currently, NYSE Arca Rule 5.2–E(j)(3) includes generic listing standards for Units based on an index or portfolio of equity or fixed

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 85170 (Feb. 21, 2019), 84 FR 6451 (''Notice'').

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 85573, 84 FR 15239 (Apr. 15, 2019). The Commission designated May 28, 2019 as the date by which the Commission shall approve or disapprove, or institute proceedings to determine whether to approve or disapprove, the proposed rule change.

[6] 15 U.S.C. 78s(b)(2)(B).

[7] For a full description of the proposed rule change, *see* Notice, *supra* note 3.

income securities or a combination thereof. Municipal Securities[8] are a type of fixed income security, and therefore currently the Exchange may generically list and trade securities overlying an index or portfolio of Municipal Securities provided the index or portfolio satisfies the criteria of Commentary .02 to NYSE Arca Rule 5.2–E(j)(3) (''Commentary .02''). According to the Exchange, however, indexes and portfolios of Municipal Securities typically do not satisfy the criterion that component securities in an index or portfolio that in aggregate account for at least 75% of the Fixed Income Securities portion of the weight of the index or portfolio each have a minimum original principal amount outstanding of $100 million or more.[9] The Exchange states that generally Municipal Securities are issued with individual maturities of relatively small size, although they typically are constituents of a much larger municipal bond offering.[10]

A. Proposed Commentary .02A to NYSE Arca Rule 5.2–E(j)(3)

1. Applicability

Proposed Commentary .02A to NYSE Arca Rule 5.2–E(j)(3) (''Commentary .02A'') provides generic listing standards for Units based on an index or portfolio of Municipal Securities. Because existing Commentary .02 also applies to Units based on an index or portfolio of Municipal Securities, the Exchange represents that it would apply existing Commentary .02 and proposed Commentary .02A in a ''waterfall'' manner. Specifically, the Exchange would initially evaluate every series of Units based on an index or portfolio of Municipal Securities or Municipal Securities and cash against the generic listing standards of existing Commentary .02 and would apply proposed Commentary .02A only to Units whose index or portfolio does not meet the requirements of Commentary .02.

2. Proposed Generic Listing Criteria

The Exchange asserts Commentary .02A includes many requirements that are more stringent than those applicable under Commentary .02. These heightened requirements, according to the Exchange, would deter potential manipulation of such Municipal Securities indices even though the index or portfolio may include securities that have smaller original principal amounts outstanding. The proposed quantitative requirements described below would apply on both an initial and continued basis to a Municipal Securities index or portfolio underlying a series of Units.

a. Original Principal Amount Outstanding

According to the Exchange, Municipal Securities are typically issued with individual maturities of relatively small size, although they generally are constituents of a much larger municipal bond offering.[11] Accordingly, the Exchange proposes to reduce the requirement for minimum original principal amount outstanding for component securities from at least $100 million to at least $5 million. Further, the Exchange proposes that qualifying securities must have been issued as part of a transaction of at least $20 million. Lastly, the Exchange proposes to increase the percentage weight of an index or portfolio that must satisfy the original principal amount outstanding requirement from 75% to 90%.

The Exchange asserts that reducing the minimum original principal amount outstanding for component securities will not make an index or portfolio more susceptible to manipulation.[12] The Exchange argues that the requirement that component securities in a Municipal Securities index or portfolio have a minimum principal amount outstanding, in concert with the other requirements of Commentary .02A, will ensure that such index or portfolio is sufficiently broad-based in scope as to minimize potential manipulation of the index or portfolio.[13] In addition, the Exchange asserts that its proposal to require that 90% of the weight of a Municipal Securities index or portfolio meet the original principal amount outstanding requirement (as opposed to 75% for existing Commentary .02) will further deter potential manipulation by ensuring that a greater portion of the index or portfolio meets this minimum size requirement.[14]

The Exchange notes that the Commission has previously approved the listing and trading of several series of Units where the underlying Municipal Securities index or portfolio required that component securities representing at least 90% of the weight of the index or portfolio have a minimum original principal amount outstanding of at least $5 million and have been issued as part of a transaction of at least $20 million.[15]

b. Component Concentration

Commentary .02, the current generic listing rules for Units based on a fixed-income index or portfolio, permits individual component securities to account for up to 30% of the weight of such index or portfolio and the top-five weighted component securities to account for up to 65% of the weight of such index or portfolio. The Exchange proposes to tighten these thresholds, proposing that under Commentary .02A an individual Municipal Security may comprise only 10% of the index or portfolio and that the five most heavily-weighted Municipal Securities in an index or portfolio may comprise only 30% of the index or portfolio. The Exchange asserts that its proposal will reduce the susceptibility to manipulation of a Municipal Securities index or portfolio underlying a series of Units.[16]

c. Issuer Diversification

The current generic listing rules for Units based on an index or portfolio of fixed-income securities require that an index or portfolio must include securities from at least 13 non-affiliated issuers. Notably, however, the current rules exempt indices consisting of either entirely exempted securities or exempted securities and cash from complying with this diversification requirement.[17] Therefore, under the current generic listing criterion, an index or portfolio comprised of only Municipal Securities (or Municipal Securities and cash) is not required to satisfy any minimum issuer diversification requirement. The Exchange proposes that an index or portfolio of Municipal Securities or Municipal Securities and cash must include securities from at least 13 non-affiliated issuers. The Exchange asserts that requiring such diversification will reduce the likelihood that an index or portfolio may be manipulated by

[8] The proposed rule defines the term ''Municipal Securities'' by incorporating the definition in Section 3(a)(29) of the Act.

[9] *See* Notice, *supra* note 3, 84 FR at 6452. ''Fixed Income Securities are debt securities that are notes, bonds, debentures or evidence of indebtedness that include, but are not limited to, U.S. Department of Treasury securities (''Treasury Securities''), government-sponsored entity securities (''GSE Securities''), municipal securities, trust preferred securities, supranational debt and debt of a foreign country or a subdivision thereof.'' NYSE Arca Rule 5.2–E(j)(3), Commentary .02.

[10] *See id.*

[11] *See supra* note 10 and accompanying text.

[12] *See* Notice, *supra* note 3, 84 FR at 6452.

[13] *See id.*

[14] *See id.* at 6453.

[15] *See* Securities Exchange Act Release No. 84049 (Sept. 6, 2018), 83 FR 46228 (Sept. 12, 2018) (SR–NYSEArca–2018–38) (order approving, among other things, revisions to the continued listing criteria applicable to the iShares New York AMT-Free Muni Bond ETF).

[16] *See* Notice, *supra* note 3, 84 FR at 6453.

[17] Municipal Securities are included in the definition of exempted securities. *See* Section 3(a)(12) of the Act.

ensuring that securities from a variety of issuers are represented in an index or portfolio of Municipal Securities.[18]

d. Minimum Number of Components

The current generic listing requirements for Units based on an index or portfolio of fixed-income securities do not have an explicit requirement that an index or portfolio contain a minimum number of securities. However, given that such rules require an index or portfolio to contain securities from at least thirteen non-affiliated issuers, there is an effective requirement that an index or portfolio of fixed-income securities contain at least thirteen component securities. As described above, a fixed-income index or portfolio comprised of exempted securities (including Municipal Securities) is not required to satisfy the issuer diversification test, and therefore such indices need not have a minimum number of component securities.

The Exchange proposes to require that a Municipal Securities index or portfolio contain at least 500 component securities. According to the Exchange, this proposed requirement will ensure that a Municipal Securities index or portfolio is sufficiently broad-based and diversified to make it less susceptible to manipulation.[19]

e. Additional Requirements

In addition to the quantitative requirements described above, the Exchange proposes to adopt additional rules related to: (1) Index methodology and calculation; (2) dissemination of information; (3) initial shares outstanding; (4) hours of trading; (5) surveillance procedures; and (6) disclosures.

The Exchange proposes to adopt Commentary .02A(b) to NYSE Arca Rule 5.2–E(j)(3), which requires that (i) if a Municipal Securities index is maintained by a broker-dealer or fund advisor, the broker-dealer or fund advisor shall erect and maintain a ''firewall'' around the personnel who have access to information concerning changes and adjustments to the index; (ii) the current index value for Units listed pursuant to proposed Commentary .02A(a) to NYSE Arca Rule 5.2–E(j)(3) will be widely disseminated by one or more major market data vendors at least once per day and, if the index value does not change during some or all of the period when trading is occurring on the NYSE Arca Marketplace, the last official calculated index value must remain available throughout NYSE Arca Marketplace trading hours; and (iii) any advisory committee, supervisory board, or similar entity that advises a Reporting Authority[20] or that makes decisions on the index composition, methodology, and related matters, must implement and maintain, or be subject to, procedures designed to prevent the use and dissemination of material non-public information regarding the applicable Municipal Securities index.

The Exchange proposes to adopt Commentary .02A(c) to NYSE Arca Rule 5.2–E(j)(3), which requires that one or more major market data vendors shall disseminate for each series of Units based on an index or portfolio of Municipal Securities an estimate, updated at least every 15 seconds during the Core Trading Session, of the value of a share of each series (the ''Intraday Indicative Value'' or ''IIV''). The Intraday Indicative Value may be based, for example, upon current information regarding the required deposit of securities and cash amount to permit creation of new shares of the series or upon the index value. The Intraday Indicative Value may be calculated by the Exchange or by an independent third party throughout the day using prices obtained from independent market data providers or other independent pricing sources such as a broker-dealer or price evaluation services. If the Intraday Indicative Value does not change during some or all of the period when trading is occurring on the Exchange, then the last official calculated Intraday Indicative Value must remain available throughout Exchange trading hours.

The Exchange proposes to adopt Commentary .02A(d) to NYSE Arca Rule 5.2–E(j)(3), which requires that a minimum of 100,000 shares of a series of Units will be required to be outstanding at commencement of trading.

The Exchange proposes to adopt Commentary .02A(e) to NYSE Arca Rule 5.2–E(j)(3), which specifies that the hours of trading for the Units will be as governed by NYSE Arca Rule 7.34–E(a).

The Exchange proposes to adopt Commentary .02A(f) to NYSE Arca Rule 5.2–E(j)(3), which specifies that Units that are listed or traded pursuant to unlisted trading privileges will be subject to the Exchange's written surveillance procedures.

Lastly, proposed Commentary .02A(g) to NYSE Arca Rule 5.2–E(j)(3) incorporates the information circular requirement of Commentary .01(g) NYSE Arca Rule 5.2–E(j)(3).

B. Proposed Amendments to Commentary .03 to NYSE Arca Rule 5.2–E(j)(3)

The Exchange also proposes to amend Commentary .03 to NYSE Arca Rule 5.2–E(j)(3) to allow the generic listing and trading of Units based on a combination of two or more types of indexes, including a combination index that includes Municipal Securities. Currently, the scope of the rule allows the Exchange to generically list Units overlying on a combination of indexes or an index or portfolio of component securities representing: (1) The U.S. or domestic equity market; (2) the international equity market; *and* (3) the fixed income market. To the extent that an index or portfolio of Municipal Securities is included in a combination, the proposed rule specifies the Municipal Securities index or portfolio must satisfy all requirements of Commentary .02A to NYSE Arca Rule 5.2–E(j)(3). The Exchange also proposes other conforming changes to Commentary .03 to NYSE Arca Rule 5.2–E(j)(3) to specify that the current requirements related to index value dissemination and related continued listing standards will apply to indexes of Municipal Securities. The Exchange notes that a combination index or portfolio that includes an index or portfolio of Municipal Securities will not be permitted to seek to provide investment results in a multiple of the direct or inverse performance of such combination index or portfolio.[21]

III. Proceedings To Determine Whether To Approve or Disapprove SR–NYSEArca–2019–04 and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act[22] to determine whether the proposed rule change should be approved or disapproved. Institution of such proceedings is appropriate at this time in view of the legal and policy issues raised by the proposed rule change. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, as described below, the Commission seeks and encourages interested persons to provide comments on the proposed rule change.

[18] *See* Notice, *supra* note 3, 84 FR at 6453.

[19] *See id.*

[20] The term ''Reporting Authority'' has the meaning given to it in NYSE Arca Rule 5.1–E(b)(16).

[21] *See* Notice, *supra* note 3, 84 FR at 6454.

[22] 15 U.S.C. 78s(b)(2)(B).

Pursuant to Section 19(b)(2)(B) of the Act,[23] the Commission is providing notice of the grounds for disapproval under consideration. The Commission is instituting proceedings to allow for additional analysis of the proposed rule change's consistency with Section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange be ''designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade,'' and ''to protect investors and the public interest.'' [24] Specifically, the Commission seeks comment regarding the following:

1. The Exchange's current generic listing requirement that at least 75% of the Fixed Income Securities portion of the weight of an underlying index or portfolio be comprised of components that each have a minimum original principal amount outstanding of $100 million is designed to ensure that adequate information is available about a substantial portion of the index components.[25] Do the Exchange' proposed alternative thresholds for Municipal Securities indexes or portfolios similarly ensure that adequate information is available about a majority of the index components? Should one or more alternative criteria be employed to achieve the objective of the current generic listing requirement?
2. Would the Exchange's proposed requirements that the underlying index or portfolio of Municipal Securities include at least 500 components from at least 13 non-affiliated issuers mitigate manipulation concerns? Should one or more alternative criteria be employed to achieve diversification sufficient to mitigate manipulation concerns?
3. Taken collectively, would the proposed generic listing criteria adequately ensure that each index or portfolio of Municipal Securities underlying an issue of Investment Company Units is not susceptible to manipulation?

IV. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal. In particular, the Commission invites the written views of interested persons concerning whether the proposed rule change is consistent with Section 6(b)(5) or any other provision of the Act, or the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b–4 under the Act,[26] any request for an opportunity to make an oral presentation.[27]

Interested persons are invited to submit written data, views, and arguments regarding whether the proposed rule change should be approved or disapproved by June 24, 2019. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by July 8, 2019. The Commission asks that commenters address the sufficiency of the Exchange's statements in support of the proposal, which are set forth in Notice,[28] in addition to any other comments they may wish to submit about the proposed rule change.

In this regard, the Commission seeks comment on the Exchange's proposed generic listing standards for Units based on an index or portfolio of Municipal Securities. The Commission specifically seeks comment on whether the proposed requirement that an underlying index or portfolio must include a minimum of 500 component Municipal Securities is consistent with the requirement that the rules of a national securities exchange be ''designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade,'' and ''to protect investors and the public interest.'' [29]

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–NYSEArca–2019–04 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–NYSEArca–2019–04. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2019–04 and should be submitted by June 24, 2019. Rebuttal comments should be submitted by June 24, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[30]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–11446 Filed 5–31–19; 8:45 am]

BILLING CODE 8011–01–P

[23] *Id.*

[24] 15 U.S.C. 78f(b)(5).

[25] *C.f.,* Securities Exchange Act Release No. 55783 (May 17, 2007), 72 FR 29194, 29199 (May 24, 2007) (order approving generic listing standards for Units based on fixed income indexes) (''The Commission believes that [the requirements of Commentary .02] are reasonably designed to ensure that a substantial portion of any underlying index or portfolio consists of securities about which information is publicly available . . .'').

[26] 17 CFR 240.19b–4.

[27] Section 19(b)(2) of the Act, as amended by the Securities Acts Amendments of 1975, Public Law 94–29 (June 4, 1975), grants the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. *See* Securities Acts Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

[28] *See supra* note 3.

[29] 15 U.S.C. 78f(b)(5).

[30] 17 CFR 200.30–3(a)(57).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15937 and #15938; KENTUCKY Disaster Number KY–00073]

Presidential Declaration Amendment of a Major Disaster for Public Assistance Only for the Commonwealth of Kentucky

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 2.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the Commonwealth of Kentucky (FEMA–4428–DR), dated 04/17/2019.

Incident: Severe Storms, Straight-Line Winds, Flooding, Landslides, and Mudslides.

Incident Period: 02/06/2019 through 03/10/2019.

DATES: Issued on 05/24/2019.

Physical Loan Application Deadline Date: 06/17/2019.

Economic Injury (EIDL) Loan Application Deadline Date: 01/17/2020.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the Commonwealth of Kentucky, dated 04/17/2019, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Nicholas, Owen.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2019–11467 Filed 5–31–19; 8:45 am]

BILLING CODE 8206–03–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15944 and #15945; MISSISSIPPI Disaster Number MS–00111]

Presidential Declaration Amendment of a Major Disaster for Public Assistance Only for the State of Mississippi

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 2.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of MISSISSIPPI (FEMA–4429–DR), dated 04/23/2019.

Incident: Severe Storms, Straight-line Winds, Tornadoes, and Flooding.

Incident Period: 02/22/2019 through 03/29/2019.

DATES: Issued on 05/22/2019.

Physical Loan Application Deadline Date: 06/24/2019.

Economic Injury (EIDL) Loan Application Deadline Date: 01/23/2020.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of MISSISSIPPI, dated 04/23/2019, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Coahoma, Leflore, Sunflower, Washington.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2019–11466 Filed 5–31–19; 8:45 am]

BILLING CODE 8206–03–P

SMALL BUSINESS ADMINISTRATION

Military Reservist Economic Injury Disaster Loans; Interest Rate for Third Quarter FY 2019

The Small Business Administration publishes an interest rate for Military Reservist Economic Injury Disaster Loans (13 CFR 123.512) on a quarterly basis. The rate will be 4.000 for loans approved on or after April 30, 2019.

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2019–11505 Filed 5–31–19; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Surrender of License of Small Business Investment Company

Pursuant to the authority granted to the United States Small Business Administration under the Small Business Investment Act of 1958, as amended, under Section 309 of the Act and Section 107.1900 of the Small Business Administration Rules and Regulations (13 CFR 107.1900) to function as a small business investment company under the Small Business Investment Company License No. 02/02–0642 issued to PennantPark SBIC, LP said license is hereby declared null and void.

United States Small Business Administration

Dated: February 28, 2019.

A. Joseph Shepard,

Associate Administrator for Investment and Innovation.

Editorial Note: The Office of the Federal Register received this document for publication on May 28, 2019.

[FR Doc. 2019–11506 Filed 5–31–19; 8:45 am]

BILLING CODE P

SMALL BUSINESS ADMINISTRATION

Surrender of License of Small Business Investment Company

Pursuant to the authority granted to the United States Small Business Administration under the Small Business Investment Act of 1958, as amended, under Section 309 of the Act and Section 107.1900 of the Small Business Administration Rules and Regulations (13 CFR 107.1900) to function as a small business investment company under the Small Business Investment Company License No. 04/04–0292 issued to Triangle Mezzanine Fund LLLP, said license is hereby declared null and void.

United States Small Business Administration

Dated: May 24, 2019.

A. Joseph Shepard,

Associate Administrator for Investment and Innovation.

[FR Doc. 2019–11507 Filed 5–31–19; 8:45 am]

BILLING CODE P

SMALL BUSINESS ADMINISTRATION

Surrender of License of Small Business Investment Company

Pursuant to the authority granted to the United States Small Business Administration under the Small Business Investment Act of 1958, as amended, under Section 309 of the Act

and Section 107.1900 of the Small Business Administration Rules and Regulations (13 CFR 107.1900) to function as a small business investment company under the Small Business Investment Company License No. 04/04–0309 issued to Triangle Mezzanine Fund II, LP, said license is hereby declared null and void.

United States Small Business Administration.

Dated: May 24, 2019.

A. Joseph Shepard,

Associate Administrator for Investment and Innovation.

[FR Doc. 2019–11508 Filed 5–31–19; 8:45 am]

BILLING CODE P

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: 30-Day notice.

SUMMARY: The Small Business Administration (SBA) is publishing this notice to comply with requirements of the Paperwork Reduction Act (PRA) which requires agencies to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public that the agency has made such a submission. This notice also allows an additional 30 days for public comments.

DATES: Submit comments on or before July 3, 2019.

ADDRESSES: Comments should refer to the information collection by name and/or OMB Control Number and should be sent to: *Agency Clearance Officer,* Curtis Rich, Small Business Administration, 409 3rd Street SW, 5th Floor, Washington, DC 20416; and *SBA Desk Officer,* Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Curtis Rich, Agency Clearance Officer, (202) 205–7030, *curtis.rich@sba.gov.*

Copies: A copy of the Form OMB 83–1, supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer.

SUPPLEMENTARY INFORMATION: Small Business Administration collects this information to assess eligibility for participation in its programs. Specifically, SBA uses the information to make a character or criminal history determination about individuals associated with an application for financial assistance or other SBA program benefits.

Title: Statement of Personal History.

Description of Respondents: Applicants participating in SBA programs.

Form Number: 912.

Estimated Annual Responses: 142,000.

Estimated Annual Hour Burden: 35,500.

Curtis Rich,

Management Analyst.

[FR Doc. 2019–11491 Filed 5–31–19; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15971 and #15972; MONTANA Disaster Number MT–00120]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of Montana

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Montana (FEMA–4437–DR), dated 05/24/2019.

Incident: Flooding.

Incident Period: 03/20/2019 through 04/10/2019.

DATES: Issued on 05/24/2019.

Physical Loan Application Deadline Date: 07/23/2019.

Economic Injury (EIDL) Loan Application Deadline Date: 02/24/2020.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 05/24/2019, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Daniels, Lake, McCone, Park, Powder River, Stillwater, Treasure, Valley.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere	2.750
Non-Profit Organizations without Credit Available Elsewhere	2.750
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	2.750

The number assigned to this disaster for physical damage is 159716 and for economic injury is 159720.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2019–11465 Filed 5–31–19; 8:45 am]

BILLING CODE 8206–03–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Membership in the National Parks Overflights Advisory Group

AGENCY: Federal Aviation Administration, (FAA), DOT.

ACTION: Solicitation of applications.

SUMMARY: The Federal Aviation Administration (FAA) and the National Park Service (NPS) invite interested persons to apply to fill one current and two upcoming vacancies on the National Parks Overflights Advisory Group (NPOAG). This notice invites interested persons to apply to fill the openings. The current opening represents Native American tribal concerns and the two upcoming openings represent air tour operator interests and environmental concerns, respectively.

DATES: Persons interested in these membership openings will need to apply by July 5, 2019.

FOR FURTHER INFORMATION CONTACT: Keith Lusk, Special Programs Staff, Federal Aviation Administration, Western-Pacific Region Headquarters, 777 S. Aviation Boulevard, Suite 150, El Segundo, CA 90245, telephone: (424) 405–7017, email: *Keith.Lusk@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The National Parks Air Tour Management Act of 2000 (the Act) was enacted on April 5, 2000, as Public Law 106–181, and subsequently amended in

the FAA Modernization and Reform Act of 2012. The Act required the establishment of the advisory group within 1 year after its enactment. The NPOAG was established in March 2001. The advisory group is comprised of a balanced group of representatives of general aviation, commercial air tour operations, environmental concerns, and Native American tribes. The Administrator of the FAA and the Director of NPS (or their designees) serve as ex officio members of the group. Representatives of the Administrator and Director serve alternating 1-year terms as chairman of the advisory group.

In accordance with the Act, the advisory group provides ''advice, information, and recommendations to the Administrator and the Director—

(1) On the implementation of this title [the Act] and the amendments made by this title;

(2) On commonly accepted quiet aircraft technology for use in commercial air tour operations over a national park or tribal lands, which will receive preferential treatment in a given air tour management plan;

(3) On other measures that might be taken to accommodate the interests of visitors to national parks; and

(4) At the request of the Administrator and the Director, safety, environmental, and other issues related to commercial air tour operations over a national park or tribal lands.''

Membership

The current NPOAG is made up of one member representing general aviation, three members representing the commercial air tour industry, four members representing environmental concerns, and two members representing Native American interests. Current members of the NPOAG are as follows:

Melissa Rudinger representing general aviation; Alan Stephen, Eric Lincoln, and Matt Zuccaro represent commercial air tour operators; Rob Smith, Dick Hingson, Les Blomberg, and John Eastman represent environmental interests; and Carl Slater represents Native American tribes with one current opening. Mr. Smith's 3-year term expires on July 4, 2019 and Mr. Zuccaro's 3-year term expires on September 9, 2019.

Selections

In order to retain balance within the NPOAG, the FAA and NPS are seeking candidates interested in filling the one vacant seat representing Native American tribal concerns and the two upcoming vacant seats representing air tour operator interests and environmental concerns. The FAA and NPS invite persons interested in these openings on the NPOAG to contact Mr. Keith Lusk (contact information is written above in **FOR FURTHER INFORMATION CONTACT**). Requests to serve on the NPOAG must be made to Mr. Lusk in writing and postmarked or emailed on or before July 5, 2019. The request should indicate whether or not you are a member of a Native American tribe, an air tour operator association or company, or whether you are a member of an environmental group or association. The request should also state what expertise you would bring to the NPOAG as related to issues and concerns with aircraft flights over national parks and/or tribal lands. The term of service for NPOAG members is 3 years. Current members may re-apply for another term.

On August 13, 2014, the Office of Management and Budget issued revised guidance regarding the prohibition against appointing or not reappointing federally registered lobbyists to serve on advisory committees (79 FR 47482).

Therefore, before appointing an applicant to serve on the NPOAG, the FAA and NPS will require the prospective candidate to certify that they are not a federally registered lobbyist.

Issued in El Segundo, CA, on May 21, 2019.

Keith Lusk,

Program Manager, Special Programs Staff, Western-Pacific Region.

[FR Doc. 2019–11499 Filed 5–31–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2003–15638]

Petition for Waiver of Compliance

Under part 211 of Title 49 Code of Federal Regulations (CFR), this document provides the public notice that on May 8, 2019, the Long Island Rail Road petitioned the Federal Railroad Administration (FRA) for an extension of an existing waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR part 238, *Passenger Car Safety Standards*. FRA assigned the petition Docket Number FRA–2003–15638.

Specifically, LIRR requests to extend the waiver from § 238.303(e)(l5)(i)(c), for its fleet of M7 multiple unit (MU) locomotives. The provision requires that MU type locomotives equipped with dynamic brakes that become defective ''shall be repaired or removed from service by or at the locomotive's next exterior calendar day mechanical inspection.'' LIRR states ''in the 15 years that this waiver has been in place, the LIRR has not encountered either reports of slow trains or handling complaints related to inactive trucks.'' LIRR contends the waiver provides ''operational flexibility without any compromise in safety or performance.'' LIRR explains it removes ''inactive trucks from service within three calendar days when practical.''

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Avenue SE, W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested parties desire an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- Website: *http://www.regulations.gov*. Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by July 18, 2019 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable.

Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.).

Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy.* See also *https://www.regulations.gov/privacyNotice* for the privacy notice of *regulations.gov.*

Issued in Washington, DC.

John Karl Alexy,

Acting Associate Administrator, Office of Railroad Safety.

[FR Doc. 2019–11458 Filed 5–31–19; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA–2019–0051]

Pipeline Safety: Information Collection Activities—Request for Extension of Existing Information Collections

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, this notice announces that the information collection requests abstracted below is being forwarded to the Office of Management and Budget (OMB) for review and comments. A **Federal Register** notice with a 60-day comment period soliciting comments on the information collections was published on March 22, 2019. PHMSA invites comments on two information collections that will be expiring in 2019. PHMSA will request an extension, without change, for the information collections identified by OMB control number 2137–0578 and 2137–0605.

During the public comment period, PHMSA received no comments in response to the information collections. PHMSA is publishing this notice to provide the public with an additional 30 days to comment on the renewal of the information collections referenced above and to announce that the information collection requests will be submitted to OMB for approval.

DATES: Interested persons are invited to submit comments on or before July 3, 2019.

ADDRESSES: You may submit comments identified by the docket number PHMSA–2019–0051 by any of the following methods:

- *Fax:* 1–202–395–5806.
- *Mail:* Office of Information and Regulatory Affairs, Records Management Center, Room 10102 NEOB, 725 17th Street NW, Washington, DC 20503, ATTN: Desk Officer for the U.S. Department of Transportation\PHMSA.
- *Email:* Office of Information and Regulatory Affairs, OMB, at the following email address: *OIRA_Submission@omb.eop.gov.*

Requests for a copy of the information collection should be directed to Angela Hill by telephone at 202–366–1246, by fax at 202–366–4566, by email at *angela.hill@dot.gov,* or by mail at U.S. Department of Transportation, PHMSA, 1200 New Jersey Avenue SE, PHP–30, Washington, DC 20590–0001.

FOR FURTHER INFORMATION CONTACT: Angela Hill by telephone at 202–366–1246, by fax at 202–366–4566, or by mail at DOT, PHMSA, 1200 New Jersey Avenue SE, PHP–30, Washington, DC 20590–0001.

SUPPLEMENTARY INFORMATION: Section 1320.8(d), Title 5, Code of Federal Regulations, requires PHMSA to provide interested members of the public and affected agencies an opportunity to comment on information collection and recordkeeping requests. This notice identifies two information collection requests that PHMSA will submit to OMB. PHMSA intends to request an extension, without change, of the information collection under OMB Control No. 2137–0578, which covers the reporting of safety-related conditions and OMB Control No. 2137–0605, which covers integrity management recordkeeping activities.

The following information is provided for each information collection: (1) Title of the information collection; (2) OMB control number; (3) Current expiration date; (4) Type of request; (5) Abstract of the information collection activity; (6) Description of affected public; (7) Estimate of total annual reporting and recordkeeping burden; and (8) Frequency of collection. PHMSA will request a three-year term of approval for each information collection activity. PHMSA requests comments on the following information collections:

1. Title: Reporting Safety-Related Conditions on Gas, Hazardous Liquid, and Carbon Dioxide Pipelines and Liquefied Natural Gas Facilities.

OMB Control Number: 2137–0578.

Current Expiration Date: 8/31/2019.

Type of Request: Renewal of a currently approved information collection.

Abstract: Each operator of a pipeline facility (except master meter operators) must submit to DOT a written report on any safety-related condition that causes or has caused a significant change or restriction in the operation of a pipeline facility, or a condition that is a hazard to life, property or the environment.

Affected Public: Operators of pipeline facilities (except master meter operators).

Annual Reporting and Recordkeeping Burden:

Estimated number of responses: 146.

Estimated annual burden hours: 876.

Frequency of collection: On occasion.

2. Title: Integrity Management in High Consequence Areas for Operators of Hazardous Liquid Pipelines.

OMB Control Number: 2137–0605.

Current Expiration Date: 10/31/2019.

Type of Request: Renewal of a currently approved information collection.

Abstract: Operators of hazardous liquid pipelines are required to conduct continual assessment and evaluation of pipeline integrity through inspection or testing, as well as remedial, preventive, and mitigative actions. This includes both recordkeeping and certain reporting requirements.

Affected Public: Operators of Hazardous Liquid Pipelines that could affect High Consequence Areas.

Annual Reporting and Recordkeeping Burden:

Estimated number of responses: 203.

Estimated annual burden hours: 325,470.

Frequency of Collection: Annually.

Comments are invited on:

(a) The need for the renewal of these collections of information for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(d) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.48.

Issued in Washington, DC, on May 22, 2019, under authority delegated in 49 CFR 1.97.

John A. Gale,

Director, Standards and Rulemaking Division.

[FR Doc. 2019–11464 Filed 5–31–19; 8:45 am]

BILLING CODE 4909–60–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 4461, 4461–A, and 4461–B

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 information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Form 4461, Application for Approval of Standardized or Nonstandardized Pre-Approved Defined Contribution Plans; Form 4461–A, Application for Approval of Master or Prototype or Volume Submitter Defined Benefit Plan; and, Form 4461–B, Application for Approval of Standardized or Nonstandardized Pre-Approved Plans.

DATES: Written comments should be received on or before August 2, 2019 to be assured of consideration.

ADDRESSES: Direct all written comments to Laurie Brimmer, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this collection should be directed to Sara Covington, (202) 317–6038, at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Sara.L.Covington@irs.gov*.

SUPPLEMENTARY INFORMATION:

Titles: Form 4461, Application for Approval of Standardized or Nonstandardized Pre-Approved Defined Contribution Plans; Form 4461–A, Application for Approval of Master or Prototype or Volume Submitter Defined Benefit Plan; and, Form 4461–B, Application for Approval of Standardized or Nonstandardized Pre-Approved Plans.

OMB Number: 1545–0169.

Form Numbers: Forms 4461, 4461–A, and 4461–B.

Abstract: The IRS uses these forms to determine from the information submitted whether the provider or mass submitter of a pre-approved defined contribution plan qualifies under section 401(a) of the Internal Revenue Code for plan approval. The application is also used to determine if the related trust qualifies for tax exempt status under Code section 501(a).

Current Actions: There are changes to the forms and burden estimates.

Type of Review: Revision of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Responses: 3,450.

Estimated Number of Respondent: 12 hours, 50 minutes.

Estimated Total Annual Burden Hours: 44,261.

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: May 28, 2019.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2019–11435 Filed 5–31–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Notice 97–45

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 information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Notice 97–45, Highly Compensated Employee Definition.

DATES: Written comments should be received on or before August 2, 2019 to be assured of consideration.

ADDRESSES: Direct all written comments to Laurie Brimmer, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the notice should be directed to Sara Covington, (202) 317–6038, at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *sara.l.covington@irs.gov*.

SUPPLEMENTARY INFORMATION:

Title: Highly Compensated Employee Definition.

OMB Number: 1545–1550.

Notice Number: Notice 97–45.

Abstract: Notice 97–45 provides guidance on the definition of highly compensated employee (HCE) within the meaning of section 414(q) of the Internal Revenue Code, as simplified by section 1431 of the Small Business Job Protection Act of 1996, including an employer's option to make a top-paid group election under section 414(q)(1)(B)(ii). The notice requires qualified retirement plans that contain a definition of HCE to be amended to reflect the statutory changes to section 414(q).

Current Actions: There are no changes being made to the notice at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, and not-for-profit institutions.

Estimated Number of Respondents: 218,683.

Estimated Time per Response: 18 minutes.

Estimated Total Annual Burden Hours: 65,605.

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: May 28, 2019.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2019–11434 Filed 5–31–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

Advisory Committee: VA National Academic Affiliations Council, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory

Committee Act that the VA National Academic Affiliations Council (NAAC) will meet via conference call on July 23, 2019, from 1:00 p.m. to 3:00 p.m. EST. The meeting is open to the public.

The purpose of the Council is to advise the Secretary on matters affecting partnerships between VA and its academic affiliates.

On July 23, 2019, the Council will discuss the Graduate Medical Education Reimbursements to Affiliates Government Accountability Office Audit; receive a status update regarding the Electronic Health Record Modernization Work Group; deliberate on VA Trainee Onboarding processes; receive briefings on the current status of Diversity and Inclusion Subcommittee efforts, VHA Telehealth Care Delivery by Trainees and the VA MISSION Act; obtain the status on Relationships with For-Profit Educational Institutions; and discuss recent efforts to oversee field Affiliation Partnership Councils. The Council will receive public comments from 2:40 p.m. to 2:50 p.m. EST.

Interested persons may attend and/or present oral statements to the Council. The dial in number to attend the conference call is: 1–800–767–1750. At the prompt, enter access code 12095 then press #. Individuals seeking to present oral statements are invited to submit a 1–2 page summary of their comments at the time of the meeting for inclusion in the official meeting record. Oral presentations will be limited to five minutes or less, depending on the number of participants. Interested parties may also provide written comments for review by the Council prior to the meeting or at any time, by email to *Larissa.Emory@va.gov,* or by mail to Larissa A. Emory PMP, CBP, MS, Designated Federal Officer, Office of Academic Affiliations (10X1), 810 Vermont Avenue NW, Washington, DC 20420. Any member of the public wishing to participate or seeking additional information should contact Ms. Emory via email or by phone at (915) 269–0465.

Dated: May 29, 2019.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2019–11474 Filed 5–31–19; 8:45 am]

BILLING CODE P

FEDERAL REGISTER

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 423 and 460

Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE); Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 423 and 460

[CMS–4168–F]

RIN 0938–AR60

Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE)

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule updates the requirements for the Programs of All-Inclusive Care for the Elderly (PACE) under the Medicare and Medicaid programs. The rule addresses application and waiver procedures, sanctions, enforcement actions and termination, administrative requirements, PACE services, participant rights, quality assessment and performance improvement, participant enrollment and disenrollment, payment, federal and state monitoring, data collection, record maintenance, and reporting. The changes will provide greater operational flexibility, remove redundancies and outdated information, and codify existing practice.

DATES: *Effective Date:* These regulations are effective on August 2, 2019.

FOR FURTHER INFORMATION CONTACT: Brandy Alston, 410–786–1218.

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose

The purpose of this final rule is to revise and update the requirements for the Programs of All-Inclusive Care for the Elderly (PACE) under the Medicare and Medicaid programs. The rule addresses application and waiver procedures, sanctions, enforcement actions and termination, administrative requirements, PACE services, participant rights, quality assessment and performance improvement, participant enrollment and disenrollment, payment, federal and state monitoring, data collection, record maintenance, and reporting. The changes will provide greater operational flexibility, remove redundancies and outdated information, and codify existing practice.

B. Summary of Key Economic Provisions

1. Compliance Oversight Requirements

Compliance programs, as found in the Medicare Advantage (MA) and Medicare Part D programs, have long been recognized as key to protecting against fraud, waste, and abuse. The importance of these programs has been highlighted by several of our oversight bodies. In the August 16, 2016 **Federal Register** (81 FR 54666), we published the proposed rule, entitled ''Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE).'' In that rule, as authorized by sections 1934(f)(3) and 1894(f)(3) of the Social Security Act (the Act), we proposed to adopt two key elements of the Part D compliance program in the PACE regulations. Specifically, we proposed to require each PACE organization (PO) to develop a compliance oversight program that will be responsible for monitoring and auditing its organization for compliance with our regulations. Additionally, we proposed to require POs to have measures that prevent, detect and correct non-compliance with CMS' program requirements, as well as measures that prevent, detect, and correct fraud, waste, and abuse. We received comments that indicated these requirements would potentially present a significant burden to POs and possibly take key staff away from providing participant care. After careful consideration of these concerns, and after re-analyzing the burden estimates, we are finalizing this provision in part.

2. Monitoring and Oversight of PACE Organizations

As a result of our experience with oversight and monitoring of the PACE program, we proposed flexibilities in connection with the current requirement that POs be monitored for compliance with the PACE program requirements during and after a 3-year trial period. We stated in the proposed rule that we must balance the responsibilities of ensuring that all of our beneficiaries are receiving quality care with our duty to effectively manage our resources and ensure proper oversight over all of the programs we manage. We proposed to use technology to enhance efficiencies in monitoring by remotely reviewing PO documents, which we have to date reviewed primarily through site visits. We also proposed to reduce the number of on-site visits after the 3-year trial period by utilizing a risk assessment to select which POs will be audited each year. We stated in the proposed rule that this risk assessment would rely primarily on an organization's past performance and ongoing compliance with CMS and state requirements. However, the risk assessment would also take into account other information that could indicate a PO needs to be reviewed, such as participant complaints or access to care concerns. We are finalizing the provisions related to federal and state monitoring as proposed.

3. Additional Flexibility for Interdisciplinary Team

This final rule makes several changes intended to expand the flexibilities of the interdisciplinary team (IDT) that comprehensively assesses and provides for the individual needs of each PACE participant. Key provisions in this final rule include permitting one individual to fill two separate roles on the IDT if the individual has the appropriate licenses and qualifications for both roles, and permitting the primary care provider that is required for each IDT to include nurse practitioners, physician assistants and community-based physicians, in addition to physicians. Another flexibility we are finalizing in this rule is removal of the requirement that members of the IDT must serve primarily PACE participants.

C. Summary of Costs and Benefits

TABLE 1—SUMMARY OF COSTS AND BENEFITS

Provision description	Total costs to POs	Total cost to government (without transfer)
Compliance Oversight Requirements.	This provision requires POs to create a compliance oversight program to allow prompt identification of non-compliance and report of fraud, waste and abuse. We estimate a one-time burden of $116,026.8 in the first year for developing the written materials and training necessary for the prompt identification and reporting of fraud, waste and abuse (124 PO × 15 hours per PO × 62.38 (hourly rate)). This cost when annualized over 3 years is $38,675.6. We further estimate an annual cost of $154,702 per year for POs reporting and responding to any suspected fraud, waste and abuse (124 PO × 20 hours per PO × $62.38 hourly rate). Thus, the total cost would be $38,675.6 initially and $154,702 afterwards.	The creation of this program does not have cost or savings to the government since it is the POs who are creating and using the compliance oversight program.
Monitoring	This provision reduces the required monitoring by CMS of POs. We estimate that there will be an annual savings to POs based on our proposal of $1,523,253. We expect 72 PO audits under the current regulations but only 35 audits as a result of this final rule. Consequently, the savings to PO would be the effort saved by not having to produce documentation and other administrative burdens that occur during an audit for 37 audits. Consequently, we are estimating the savings per audit for a PO to be approximately $41,169 (1 Nurse Manager at $53.69/hour × 2 (Factor for fringe benefits) × 150 hours per person plus 1 Executive Assistant at $28.56/hour × 2 (Factor for fringe benefits) × 150 hours per person) plus 1 Medical Record Technician at 20.59/hour × 2 (Factor for Fringe benefits) × 150 hours per person plus 1 Compliance Officer at 34.39/hour × 2 (Factor for Fringe benefits) × 150 hours per person). Therefore, the total savings to POs will be $41,169 × 37 = $1,523,253.	We estimate an annual savings of $2,638,144 to the government. We expect 72 PO audits under current regulations. We expect only 35 audits under this final rule. The savings to the government would be the effort saved by not having to perform 37 audits. The cost per audit is 2 GS–13 × $1,980 travel + 200 hours for GS–13s × $46.46/hr GS–13 wage × 2 (Fringe benefit factor) + 60 hours for GS–15s × $64.59/hr GS–15 wage × 2 (Fringe benefit factor) + 20 hours for 1 GS–13 × 46.46/hr GS–13 wage × 2 (Fringe benefit factor) = $71,301.20. Hence, the total savings is $71,301.20 × 37 = 2,638,144. The audit work includes all of the pre-audit work, including (i) compiling and (ii) submitting audit documentation; (iii) 2 weeks of audit fieldwork; the post-audit work of (iv) collecting and (v) submitting impact analyses, (vi) reviewing and (vii) commenting on the draft audit report, and (viii) submitting and (ix) implementing corrective action plans for conditions of non-compliance.
Additional Flexibility for the Inter-disciplinary Team (IDT).	This provision provides administrative flexibility for POs without compromising care by: (i) Permitting one individual to fill two separate roles on the IDT if the individual has the appropriate licenses and qualifications for both roles; (ii) permitting the primary care provider (required for each IDT) to include nurse practitioners, physician assistants and community-based physicians, in addition to physicians; and (iii) removing the requirement that members of the IDT must serve primarily PACE participants. While this provision provides greater flexibility in creating the IDT, it does not create cost or savings.	This provision has neither cost nor savings to the government due to the fact that many POs are currently exercising these flexibilities through PACE waivers.
Participant Assessments	The provision provides clarity on initial assessments, removes duplicative requirements for periodic reassessments, and provides greater flexibility for unscheduled reassessments. More specifically: The provision clarifies that: (i) Initial assessments must be done in-person and prior to completion of the plan of care (within 30 days); (ii) reassessments must be done semi-annually and requires a minimum of three IDT members; (iii) "change in participant status" reassessments require a minimum of three (instead of eight) IDT members; and (iv) remote technology may be used to conduct certain reassessments for participant requests that will likely be deemed necessary to improve or maintain the participants overall health status. The use of remote technologies to conduct these reassessments for participant requests under § 460.104(d)(2) results in savings from reduced travel costs for PO staff and PACE participants. We are scoring this as a qualitative savings since there are challenges with quantifying it. Similarly, the other provisions are qualitative savings to POs.	These provisions will not result in additional costs or savings to the government.

TABLE 1—SUMMARY OF COSTS AND BENEFITS—Continued

Provision description	Total costs to POs	Total cost to government (without transfer)
PACE Program Agreement—Include Medicaid Rate Methodology.	This provision provides states and POs the ability to adapt to potential payment rate changes and variations by allowing the inclusion of the Medicaid payment rate methodology in the PACE program agreement instead of the actual rates. Although this provision may reduce the burden of POs having to update agreements to include the actual Medicaid payment rates, this is not a mandatory requirement and we are not scoring this change since some states may elect to continue to include the Medicaid rates.	Since this is an option on the part of states, and some states may continue to elect to include the actual Medicaid rates in the program agreement, and because CMS will continue to review and approve state Medicaid PACE capitation rates, there is neither cost nor savings to the government.
Enforcement Actions	This provision allows CMS the discretion to take less punitive action, such as sanctions or CMPs, when authorized to terminate a PO. Because the provision authorizes lesser sanctions under the existing disciplinary process, the provision has neither cost nor savings to POs.	Because the provision authorizes lesser sanctions under the existing disciplinary process, the provision has neither cost nor savings to the government.
Application Process	This provision allows an electronic and automated PACE application and waiver process. Since this provision codifies existing practice it results in neither costs nor savings.	This provision codifies existing practice, and therefore, has neither cost nor savings to the government.
PACE Marketing	The provision strengthens beneficiary protections by prohibiting POs from: (i) Using agents/brokers that are not directly employed by the PO to market PACE programs, unless appropriately trained; (ii) unsolicited marketing by direct contact, including phone calls and emails. Since the purpose of prohibiting these marketing practices is to strengthen existing beneficiary protections, this provision is not considered a cost or savings.	This provision has neither cost nor savings to the government.

II. Background

A. Program Description

The PACE program is a unique model of managed care service delivery for the frail elderly, most of whom are dually-eligible for Medicare and Medicaid benefits, and all of whom are assessed as being eligible for nursing home placement according to the Medicaid standards established by their respective states.

B. Legislative and Regulatory History

1. Demonstration Project

Section 603(c) of the Social Security Amendments of 1983 (Pub. L. 98–21), as extended by section 9220 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA) (Pub. L. 99–272), authorized the original demonstration PACE program for On Lok Senior Health Services (On Lok) in San Francisco, California. Section 9412(b) of the Omnibus Budget Reconciliation Act (OBRA) of 1986 (Pub. L. 99–509), authorized CMS to conduct a PACE demonstration program to determine whether the model of care developed by On Lok could be replicated across the country. The number of sites was originally limited to 10, but the OBRA of 1990 (Pub. L. 101–508) authorized an increase to 15 PACE demonstration programs. The PACE demonstration program was operated under a Protocol published by On Lok, Inc. as of April 14, 1995.

The PACE model of care includes, as core services, the provision of adult day health care and IDT care management, through which access to and allocation of all health services is managed. Physician, therapeutic, ancillary, and social support services are furnished in the participant's residence or on-site at a PACE center. Hospital, nursing home, home health, and other specialized services are generally furnished under contract. Financing of the PACE demonstration model was accomplished through prospective capitation payments under both Medicare and Medicaid. Under section 4118(g) of the OBRA of 1987 (Pub. L. 100–203), PACE demonstration programs had to assume full financial risk progressively over the initial 3 years. As such authority was removed by section 4803(b)(1)(B) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), PACE demonstration programs approved after August 5, 1997 had to assume full financial risk at start-up.

2. Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33)

Section 4801 of the BBA authorized coverage of PACE under the Medicare program by amending title XVIII of the Act to add section 1894 of the Act, which addresses Medicare payments and coverage of benefits under PACE. Section 4802 of the BBA authorized the establishment of PACE as a state option under Medicaid by amending title XIX of the Act and adding section 1934 of the Act, which directly parallels the provisions of section 1894 of the Act. Section 4803 of the BBA addresses implementation of PACE under both Medicare and Medicaid, the effective date, timely issuance of regulations, priority and special consideration in processing applications, and extension and transition for PACE demonstration project waivers.

As directed by section 4803 of the BBA, we published an interim final rule with comment period (IFC) on November 24, 1999, establishing requirements for PACE under sections 1894 and 1934 of the Act (64 FR 66234). The 1999 IFC was a comprehensive rule that addressed eligibility, administrative requirements, application procedures, services, payment, participant rights, and quality assurance under PACE.

3. The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554)

The following three sections of BIPA modified the PACE program:

- Section 901 extended the transition period for the PACE demonstration programs to allow an additional year for these organizations to transition to the permanent PACE program.
- Section 902 gave the Secretary of Health and Human Services (the Secretary) the authority to grandfather in the modifications these programs had implemented as of July 1, 2000. This provision allowed the PACE demonstration programs to continue

program modifications they had implemented and avoid disruptions in participant care where these modifications were determined to be consistent with the PACE model.

• Section 903 specifically addressed flexibility in exercising the waiver authority provided under sections 1894(f)(2)(B) and 1934(f)(2)(B) of the Act. It authorized the Secretary to modify or waive PACE regulatory provisions in a manner that responds promptly to the needs of PACE organizations (POs) relating to the areas of employment and the use of community-based primary care physicians. Section 903 of BIPA also established a 90-day review period for waiver requests. On October 1, 2002, we issued an IFC to implement section 903 of BIPA (67 FR 61496).

4. Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173)

On December 8, 2003, Congress enacted the MMA. Several sections of the MMA affected POs. Most notably, section 101 of the MMA affected the way in which POs are paid for providing certain outpatient prescription drugs to any Part D eligible participant. The MMA altered the payment structure for Part D drugs for POs by shifting the payer source for PACE enrollees who are full-benefit dual-eligible individuals from Medicaid to Medicare, and, in part, from the beneficiary to Medicare for individuals that are not full-benefit dual-eligible beneficiaries who elect to enroll in Part D. The MMA did not affect the manner in which POs are paid for the provision of outpatient prescription drugs to non-part D eligible PACE participants.

Section 101 of the MMA added section 1860D–21(f) of the Act, which provides that POs may elect to provide qualified prescription drug coverage to enrollees who are Part D eligible individuals. The MMA allows CMS the flexibility to deem POs as MA plans with prescription drug coverage (MA–PD) local plans and to treat POs that elect to provide qualified drug coverage in a manner similar to MA–PD local plans. Due to inconsistencies in the PACE and MMA statutes, we chose to treat POs in a similar manner as MA–PD plans, thereby avoiding conflicting requirements. The requirements that apply to POs that elect to provide qualified prescription drug coverage to Part D eligible enrollees are described in section II.T.3. of the January 2005 Part D final rule (70 FR 4426 through 4434).

In addition, section 236 of the MMA amended the Act to extend to POs the existing statutory Medicare and Medicaid balance billing protections that had previously applied to POs under the PACE demonstration program authority.

Section 301 of the MMA amended the Medicare Secondary Payer (MSP) provisions in section 1862(b) of the Act. These amendments clarify the obligations of primary plans and primary payers, the nature of the insurance arrangements subject to the MSP rules, the circumstances under which Medicare may make conditional payments, and the obligations of primary payers to reimburse Medicare. To implement section 301 of the MMA, we issued an IFC published in the February 24, 2006 **Federal Register** (71 FR 9466). The provisions in the IFC were finalized in a final rule published in the February 22, 2008 **Federal Register** (73 FR 9679). The IFC revised pertinent MSP regulations found at 42 CFR part 411. Our PACE regulations at § 460.180(d) specify that Medicare does not pay for PACE services to the extent that Medicare is not the primary payer under part 411. The MSP regulations found at 42 CFR part 411 set forth our current policies regarding MSP obligations involving other payers.

5. 2006 PACE Final Rule

On December 8, 2006, we issued a final rule (71 FR 71244) (hereinafter 2006 final rule) that finalized both the PACE IFC published in the November 24, 1999 **Federal Register** (64 FR 66234) and the PACE IFC published in the October 1, 2002 **Federal Register** (67 FR 61496).

For a complete history of the PACE program, please see the 2006 final rule (71 FR 71244 through 71248).

C. PACE Regulatory Framework

Sections 1894(f) and 1934(f) of the Act set forth the requirements for issuing regulations to carry out sections 1894 and 1934 of the Act. Sections 1894(f)(2) and 1934(f)(2) of the Act state that the Secretary must incorporate the requirements applied to PACE demonstration waiver programs under the PACE Protocol when issuing interim final or final regulations, to the extent consistent with the provisions of sections 1894 and 1934 of the Act. However, the Secretary may modify or waive these provisions under certain circumstances. Sections 1894(a)(6) and 1934(a)(6) of the Act define the PACE Protocol as the Protocol for PACE as published by On Lok, Inc., as of April 14, 1995, or any successor protocol that may be agreed upon between the Secretary and On Lok, Inc. We issued the 1999 and 2002 IFCs and the 2006 final rule under authority of sections 1894(f) and 1934(f) of the Act.

We believe sections 1894(f) and 1934(f) of the Act primarily apply to issuance of the initial interim and final PACE program regulations because they refer to the PACE Protocol,[1] which has now been replaced by the PACE program agreement.[2] Sections 1894(f)(2)(B) and 1934(f)(2)(B) of the Act permit the Secretary to modify or waive provisions of the PACE Protocol as long as any such modification or waiver is not inconsistent with and does not impair any of the essential elements, objectives, and requirements of the PACE Protocol and, in particular, does not modify or waive any of the following five provisions:

• The focus on frail elderly qualifying individuals who require the level of care provided in a nursing facility.

• The delivery of comprehensive integrated acute and long-term care services.

• The IDT approach to care management and service delivery.

• Capitated, integrated financing that allows the PO to pool payments received from public and private programs and individuals.

• The assumption by the PO of full financial risk.

While we believe sections 1894(f) and 1934(f) of the Act no longer have direct application to the PACE program in many respects, we believe the limitations on waivers and modifications continue to apply to updates to the PACE program to the extent the updates concern essential elements, objectives, and requirements of the PACE Protocol, as replaced by the PACE program agreement, or any of the five listed provisions.

III. Summary of the Provisions of the Proposed Rule, and Analysis of Responses to Public Comments

In the August 16, 2016 proposed rule, we proposed to revise and update the policies finalized in the 2006 final rule to reflect subsequent changes in the practice of caring for the frail and elderly and changes in technology (for example, the use of electronic communications, including email, and the automation of certain processes) based on our experience implementing and overseeing the PACE program. We explained in the proposed rule that PACE has proven successful in keeping frail, older individuals, many of whom are eligible for both Medicare and

[1] *https://www.gpo.gov/fdsys/pkg/FR-1999-11-24/pdf/99-29706.pdf* (Addendum A).

[2] *https://www.cms.gov/Medicare/Health-Plans/pace/downloads/programagreement.pdf.*

Medicaid benefits (dual eligibles), in community settings.[3] However, it is necessary to revise some regulatory provisions to afford more flexibility to POs and state administering agencies (SAAs) as a means to encourage the expansion of the PACE program to more states, thus increasing access for participants, and to further enhance the program's effectiveness at providing care while reducing costs. Therefore, we proposed a number of flexibilities, including allowing non-physician medical providers practicing within the scope of their state licensure and clinical practice guidelines to serve in place of primary care physicians in some capacities, and permitting POs to better tailor the IDTs to improve efficiency, while continuing to meet the needs of their participants.

We received approximately 110 public comments on the proposed rule from POs, individuals, health care providers, advocacy groups, and states. In the sections that follow, we describe each proposed provision, summarize any public comments received on each provision, and provide our responses to the comments.

A. Global Change Regarding Quality Assessment and Performance Improvement

Part 460 encompasses the regulatory provisions pertaining to PACE. We proposed to replace all references to ''quality assessment and performance improvement'' in part 460 of the regulations (including subpart and section headings) with ''quality improvement.'' We noted in the proposed rule that we proposed this change because, in practice, the term ''quality improvement'' is used by the POs, SAAs, CMS, and the industry when referring to quality assessment and performance improvement for POs. Furthermore, the term ''quality improvement'' is used to mean the same thing in other CMS programs, such as the CMS Quality Improvement Organization Program and the MA Quality Improvement Program, so this change would allow for consistency in use of language across CMS programs. We stated that this would be a change in terminology only and would not designate a change in the requirements for the PACE quality program. As proposed, the change would affect the following sections and headings in the current regulations: §§ 460.32(a)(9), 460.60(c), 460.62(a)(7), 460.70(b)(1)(iii), 460.120(f), 460.122(i), 460.130(a), 460.132(a) and (c)(3), 460.134(a), 460.136(a), (b), (c), (c)(1) and (2), 460.138(b), and 460.172(c), and the headings of subpart H and §§ 460.132, 460.134, and 460.136. We noted in the proposed rule that, because we were proposing to remove § 460.140 in its entirety, we would not need to change the reference in that section.

As we received no comments on this global change, we are finalizing it as proposed.

B. Subpart A—Basis, Scope, and Definitions

1. Part D Program Requirements (§ 460.3)

In the 2006 final rule (71 FR 71248), we indicated that MA–PD requirements with respect to Part D prescription drug coverage would apply to POs that elect to provide qualified Part D prescription drug coverage. However, the PACE regulations make no mention of Part D program requirements. To clarify this policy, we proposed to add § 460.3, ''Part D Program Requirements,'' to state that the POs offering qualified prescription drug coverage and meeting the definition of a Part D plan sponsor (as defined at § 423.4) must abide by all applicable Part D program requirements in 42 CFR part 423. We explained in the proposed rule that when we issue Part D program guidance we often receive questions regarding applicability to PACE, and it has been our experience that POs are not always aware they must comply with Part D requirements unless a specific requirement has been waived. (For a list of the Part D regulatory requirements that are waived for POs, see section 2.4 of the Part D application for new POs, available at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ApplicationGuidance.html*.) We stated that we believed the proposed change is consistent with our current policy and does not involve any change in the current treatment of POs offering qualified Part D prescription drug coverage.

The following is a summary of the public comments we received on the proposed provision regarding Part D program requirements and our responses to comments.

Comment: Several commenters generally supported the proposal to include in the PACE regulations the requirement that POs offering Part D qualified prescription drug coverage comply with Part D program requirements in 42 CFR part 423. However, one commenter requested that the regulatory text include a list of Part D requirements that are waived for PACE and suggested that CMS issue Health Plan Management System (HPMS) guidance specifying which Part D requirements are applicable to PACE. The same commenter requested that CMS audits take into account differences between PACE and MA–PDs and Medicare prescription drug plans (PDPs). The commenter also requested that CMS help in reducing Part D premiums and other costs for PACE participants.

Response: Regarding the suggestion to list in the PACE regulations the specific Part D requirements that are waived for PACE, we prefer to maintain our current approach of listing the waived regulations in the Part D application for new POs, as well as the PACE program agreement. We believe our approach provides greater administrative flexibility (for example, to remove or add waived requirements) than if we codified the list in regulation. Further, we believe listing the waived regulations in the Part D PACE application is appropriate so that this information is readily available to all entities submitting an application. However, we agree that when we need to change how a waiver of Part D requirements is applied in PACE, or revoke a waiver based on new information or legal requirements, we should issue guidance to address those changes. For example, we will be issuing an HPMS memo to clarify the requirements for drug management programs in PACE to reflect the regulatory changes made in the final rule to implement the Comprehensive Addiction and Recovery Act (CARA) (83 FR 16440). Because the other comments concerning audits and assistance with reducing premiums and other costs address topics that were not covered in our proposal, we consider those comments to be outside the scope of this rule. We are finalizing the new § 460.3 as proposed, with one technical change to refer to the definition of a Part D sponsor ''in'' § 423.4 instead of ''at'' § 423.4.

C. Subpart B—PACE Organization Application and Waiver Process

1. Purpose (§ 460.10)

Section 460.10 describes the purpose of subpart B, which sets forth the processes for an entity to apply to become a PO and to apply for a waiver of certain regulatory requirements. We proposed to revise this section to add a new paragraph (a) to address the

[3] See the Medicare Payment Advisory Commission's June 2012 Report to the Congress, Medicare and the Health Care Delivery System, pp. 76–77, available at *http://www.medpac.gov/docs/default-source/reports/june-2016-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf.*

application process and a new paragraph (b) in which we proposed to move the current language in this section regarding the waiver process by which a PO may request a waiver of certain regulatory requirements. We also proposed to add § 460.10(a)(2) and (3) to describe the process for a PO to seek approval from CMS to expand an existing service area or add a new PACE center. We did not receive any comments on this proposal, and therefore, we are finalizing it as proposed.

2. Application Requirements (§ 460.12)

Section 460.12 sets forth the application requirements for an organization that wishes to participate in the PACE program. Section 460.12(a) currently requires an individual authorized to act for an entity to submit a complete application to CMS that describes how the entity meets all requirements in part 460 if the entity seeks approval from CMS to become a PO. As set forth in our PACE manual, an application must also be submitted for a PO that seeks to expand its service area and/or add a new PACE center site (see PACE Manual, Ch. 17, Sections 20.4 through 20.7). There are three scenarios specified in the PACE manual under which a PO may expand operations: (1) It may expand its geographic service area without building additional sites; (2) it may open another physical site in the existing geographic service area; and (3) it may expand its geographic service area and open another physical site in the expanded area. Currently, POs are required to submit an application to CMS and the SAA to expand their geographic service area and/or add a new PACE center to their PO. In October 2004, we released the PACE expansion application, which was for existing POs that wish to expand their geographic service areas, and/or add a new PACE center to their PO.

As with initial applications, our guidance requires POs to submit an expansion application to CMS through the SAA. However, current regulations do not specify a process for POs to submit, and the SAA and CMS to approve, an expansion application. Therefore, we proposed to amend § 460.12(a) to specify that it also applies to expansion applications submitted by existing POs that seek to expand their service area and/or to add a PACE center site. Specifically, we proposed to add language in § 460.12(a) that an individual authorized to act for a PO that seeks to expand its service area and/or add a PACE center site must submit a complete application to CMS that describes how the PO meets all requirements in this part. We stated in the proposed rule that we believed including this requirement in § 460.12 will help ensure POs understand our current practice of requiring an expansion application for a PO that seeks to expand its service area and/or add a PACE center site.

We also proposed to add the phrase ''in the form and manner specified by CMS'' to § 460.12(a) when describing the submission to CMS of a complete application to become a PO or to expand a service area and/or add a PACE center, to allow for submission of applications and supporting information in formats other than paper, which was the required format at the time the proposed rule was issued. As we explained in the proposed rule, paper applications were often hundreds of pages long, expensive to reproduce and transmit, and administratively inefficient, as staff reviewing different parts of the application are located in different physical locations and must receive hard copies of the material. We noted that to adapt to the increased use of electronic communications, electronic health records, and electronic data storage and exchange, we must continuously update the form and manner by which we administer our programs. We stated that we had successfully transitioned the MA application and PDP application to a fully electronic submission process, enabling a more organized and streamlined review, and wanted to bring those same efficiencies to the PACE application process. We also noted that we will provide further guidance on this process through HPMS or similar electronic system that may replace HPMS. Effective March 31, 2017, the first quarterly application submission date, we required POs to submit all applications electronically via HPMS, including initial applications, and applications for existing POs to expand their service area and/or add a PACE center site. POs and applicants may also refer to the CMS online tools for application submission at *https://www.cms.gov/Medicare/Health-Plans/PACE/Overview.html.*

Section 460.12(a)(2) provides that we would accept applications from entities that seek approval as POs beginning on February 22, 2000, except we would accept applications on earlier dates for certain entities that qualify for priority processing or special consideration. We established this provision and two other sections of the PACE regulations, previously found at § 460.14 and § 460.16, to implement section 4803(c) of the BBA of 1997. Section 4803(c) directed us to give priority in processing applications, during the 3-year period following enactment of the BBA of 1997, to PACE demonstration programs and then to entities that had applied to operate a PACE demonstration program as of May 1, 1997. In addition, section 4803(c) of the BBA of 1997 required that we give special consideration in the processing of applications during the 3 years following enactment to any entity that as of May 1, 1997, had indicated specific intent to become a PO through formal activities such as entering into contracts for feasibility studies. In the 2006 final rule (71 FR 71253), we deleted § 460.14 (Priority Consideration) and § 460.16 (Special Consideration) because the authority to provide these considerations expired on August 5, 2000. For the same reason, in the proposed rule, we proposed to delete paragraph (a)(2) of § 460.12, as it is no longer applicable.

Section 460.12(b) provides that an entity's application must be accompanied by an assurance from the SAA of the state in which the program is located indicating that the state (1) considers the entity to be qualified to be a PO and (2) is willing to enter into a PACE program agreement with the entity. However, we have received applications without the required SAA assurance. To help ensure that our current policy is clear, we proposed to revise the language to require that the entity's application to become a PO include an assurance from the SAA that the state considers the entity to be qualified to be a PO and the state is willing to enter into a PACE program agreement with the entity. We explained in the proposed rule that we want entities to understand we would not consider an application to become a PO to be complete without assurance from the SAA that the state both considers the entity to be qualified to be a PO and is willing to enter into a PACE program agreement with the entity. We noted that we would not review applications that do not include this assurance.

Similarly, we proposed to redesignate paragraphs (b)(1) and (2) as § 460.12(b)(1) and add a new paragraph (b)(2) to codify the current requirement in the PACE expansion application that a PO's application to expand its service area and/or add a new PACE center site must include an assurance from the SAA that the state is willing to amend the PACE program agreement to include the new PACE center sites and/or expand the PO's service area. We noted that we also expect, as we stated in the preamble to the 1999 IFC for initial applications (64 FR 66238), that the SAA will verify that an applying entity has qualified administrative and clinical

staff employed or under contract prior to furnishing services to participants in the expanded service area.

In addition, we proposed to move the language in § 460.22, which requires an entity to state in its application the service area it proposes for its program, and provides that CMS (in consultation with the SAA) may exclude an area already covered under another PACE program agreement, to proposed paragraph § 460.12(c) and remove § 460.22. As proposed, § 460.12(c)(1) would specify that both an entity submitting an application to become a PO and a PO submitting an application seeking to expand its service area must describe the proposed service area in their application. We also proposed to make a corresponding change to the Medicare Part D definition of ''Service area'' in § 423.4 for PACE plans offering qualified prescription drug coverage by removing the reference to ''§ 460.22 of this chapter'' and adding in its place ''§ 460.12(c) of this chapter,'' as our proposed changes would move the language currently in § 460.22 to § 460.12(c).

Finally, to codify CMS' current practice regarding the permissibility of POs to expand their service area and/or add a new PACE center site (see PACE Manual, Ch. 17, Section 20.4), we proposed to add § 460.12(d), which would provide that CMS and the SAA will only approve an expansion application after the PO has successfully completed its first trial period audit and, if applicable, has implemented an acceptable corrective action plan.[4]

We stated in the proposed rule that we believed all of these changes to § 460.12 would streamline the regulations and make the requirements clear and consistent with the PACE statutes. We noted that we will provide subregulatory guidance on application submission requirements after publication of the final rule.

A discussion of the comments we received on the proposed changes to the application requirements, and our responses to those comments, appears below.

Comment: One commenter questioned how the state will ensure that the required state assurance that is to accompany an initial or expansion application is accurate without additional monitoring. The commenter also questioned if the state will be required to perform additional monitoring (with supporting documentation) to prove that an expanding PO is indeed qualified to expand its service area or add an additional PACE center.

Response: The PACE regulations currently require that an entity's application to become a new PO be accompanied by an assurance from the SAA that the state considers the entity to be qualified to be a PO and is willing to enter into a PACE program agreement with the entity. In proposing to revise § 460.12(b), we sought to clarify in the regulations that, similar to the requirement for an initial application, the SAA must provide an assurance to us that the state is willing to expand the existing PACE program agreement to add to an existing service area and/or add a new PACE center. Given that we, in cooperation with the SAA, already conducts ongoing monitoring of a PO, we expect the state will determine what if any additional information is needed from a PO before providing the required assurance. As required by Chapter 17 of the PACE manual (Sections 10, 20.6, 20.7 and 30.2), if the PO is seeking to expand by adding a new PACE center, the SAA is responsible for conducting the state readiness review (SRR) of the PACE center to ensure that it meets the regulatory requirements for environment and staffing, and must provide the results to us before the expansion application can be approved.

Comment: Some commenters expressed support for CMS' proposal to modernize the application process for entities that seek to become new POs or to expand existing service areas or add new PACE center sites, acknowledging that the electronic exchange of information will expedite the processing of applications and be less burdensome for both POs and CMS.

Response: We thank the commenters for their support.

Comment: A variety of commenters, including PACE associations, supported the proposed requirements related to the submission of initial applications by entities seeking to become POs, as well as applications submitted by POs to expand their geographic service areas. Commenters recommended that CMS not require a PO to submit a formal expansion application in order to add a new PACE center within an existing service area. Commenters suggested that instead of requiring an expansion application for a new PACE center, CMS only require a PO to provide advance notification (a minimum of 60 days in advance) at any time (not limited to the quarterly application submission cycle), and report specific information (for example, location of the new PACE center, SAA assurance of support, willingness to amend the PACE program agreement, attestation of financial solvency with supporting documentation as evidence of the program's financial capacity, etc.), along with a completed SRR prior to the opening of the new PACE center. Commenters suggested that subsequently, but still prior to the new PACE center's opening, the PO would submit any revised marketing materials to CMS for review. Some commenters also suggested that a similar process, with no expansion application requirement, would be sufficient for circumstances in which a PO is simply moving a PACE center to a new location and relocating the IDT. Other commenters noted that removing the current requirement to submit applications on a quarterly cycle would enable POs to open a new PACE center more quickly to build capacity in response to increasing enrollment.

Response: We do not agree with the suggestion to remove the expansion application requirement for existing POs seeking to add a new PACE center within an existing service area for a number of reasons. First, the submission of an expansion application in which the PO seeks to add a new PACE center in an existing service area ensures that a structured, formalized process is employed consistently, regardless of expansion type, and ensures that the PO is providing proper assurances that PACE requirements are being met and that appropriate documentation is provided and included as part of the PACE program agreement. Furthermore, an expansion application requirement benefits both CMS and the PO, as both parties are held accountable and are required to adhere to established timeframes and deadlines. Perhaps most importantly, the submission of a formal expansion application, regardless of type, enables us to make a determination based on a standardized mechanism and affords the PO the opportunity to request reconsideration of denials by us. Regarding commenters' suggestion that a similar alternative process, with no expansion application requirement, could also be employed when a PO is simply moving a PACE center to a new location and relocating the IDT, we would point to our guidance that addresses expectations of POs under these circumstances. (See the October 21, 2016 HPMS memorandum, PACE Replacement Center Transition Guidance.) POs that seek to relocate an existing PACE center should follow this subregulatory guidance.

Comment: A commenter suggested that the SRR be appropriately tailored to situations in which a PO is applying to

[4] The PACE manual is available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/internet-Only-Manuals-IOMs-Items/CMS019036.html.*

either expand its service area or add a new PACE center site, stating that the SRR in these instances should not be the equivalent to an SRR conducted for and included in an initial application.

Response: We note that an SRR is not required for service area expansion (SAE) applications that do not include the addition of a new PACE center. We recognize that the SRR is typically the primary driver of delay in final approval when a PO applies for an expansion that includes the addition of a new PACE center site. However, the SRR is also a critical component of an expansion application that includes a new PACE center, as it assures that all state-based licensure requirements are met and building and safety codes are satisfied. The SRR primarily consists of reviewing requirements specific to the PACE center itself, such as construction, equipment and maintenance to assure physical safety of participants and personnel. While there are some SRR requirements that may remain the same as the existing PACE center(s), such as transportation, contracts and policies and procedures, that may not be the case if the new PACE center is geographically distant from the existing PACE center. For example, there may be a different transportation provider or other new contractors that are more accessible to the new PACE center location. Because of those variables, we believe it would be difficult to tailor the current SRR for an expansion application that includes addition of a new PACE center.

Comment: Some commenters requested that CMS specify in § 460.12 that an expansion application will not have to include information previously submitted to CMS as part of the initial application. Another commenter noted that streamlining the administrative process removes a burden for both POs and CMS in processing these applications.

Response: While SAE applicants were previously required to submit a smaller subset of documents than initial PACE applicants, in March 2018, as part of the first quarterly application submission cycle, CMS began requiring SAE applicants to respond to the same attestations and upload the same documentation as initial PACE applicants. The PACE program agreement is the binding document between the PO, CMS and the SAA. We have found that program agreements, particularly for POs that have been active for some time, may not fully represent current operational policies and procedures and other information that is required content of the program agreement under § 460.32. We understand commenters' concerns regarding the potential burden associated with SAE applicants having to upload documents previously submitted as part of an initial application. However, in addition to providing added assurance and evidence that an active PO is qualified to expand its PACE program, we believe the application process is an appropriate, efficient and effective vehicle for capturing documentation that is required as part of the PO's PACE program agreement, including changes to operational policies and procedures, and eliminates the need to require the PO to submit additional information separately. While not explicitly addressed in this rule, we note that comments received from the PACE industry in response to an information collection request (CMS–10631, OMB 0938–1326) regarding this approach for SAE applications have generally indicated support for requesting information as part of the SAE application itself in order to facilitate efforts to update the PACE program agreement. This information collection request is subject to renewal and expires on December 31, 2021.

We believe this approach results in a more streamlined process and reduced burden for all parties to the PACE program agreement.

Comment: Commenters expressed support for the proposed provision in § 460.12(d), which would require a PO to have completed its first trial period audit and, if applicable, implemented an acceptable corrective action plan before CMS and the SAA will approve a service area expansion or PACE center expansion, with two specific modifications. Commenters requested an exception to this requirement when the PO is relocating its PACE center to a new location due to unforeseen circumstances or to assure adequate access if program growth exceeds enrollment projections. In addition, because the timing of the first trial period audit affects the ability of a PO to grow, commenters requested that CMS and the SAA commit to conducting trial period audits in a timely manner, with an expectation that the first year audit be completed no later than 15 months after the opening of the PACE program.

Response: We appreciate the support for the proposed provision in § 460.12(d) and acknowledge that unforeseen or otherwise exceptional circumstances, such as storm damage from a hurricane, may require a PO to immediately relocate its PACE center prior to completion of the first trial period audit. In situations that constitute emergency events, we would expect the PO to implement its emergency preparedness plan under § 460.84, which should include established plans and procedures for continued care of all participants, including those who had previously required regular PACE center attendance, as well as those who predominantly or exclusively receive care at home or in alternative care settings, as applicable. In the event such emergency circumstances require the relocation of a PACE center, either on a temporary or permanent basis, we would work with the PO and the SAA to ensure that the PO's emergency preparedness plan is implemented effectively and in a manner that maintains the health and safety of participants and staff. Such circumstances vary widely and present unique challenges; and we will expect the PO, to the extent possible, to address the items identified in the transition plan included as part of the October 21, 2016 HPMS memorandum, PACE Replacement Center Transition Plan guidance, while recognizing that the guidance may need to be tailored in response to the emergency situation presented. The priority under such circumstances will be to ensure that participants continue to receive necessary medical care and IDT members are able to continue to function and serve the needs of participants in a safe environment, regardless of setting. We would not require submission of an expansion application in this type of emergency situation, and do not believe it is necessary to amend § 460.12(d) to address unforeseen or otherwise exceptional circumstances.

We also do not agree that an exception should be made to allow relocation of a PACE center prior to completion of the first trial period audit in order to assure adequate access if program growth exceeds enrollment projections. A PO that intends to relocate its PACE center in order to satisfy increased enrollment demands would be required to wait until the first trial period audit is successfully completed. We believe this is reasonable because it enables us to ensure the PO is satisfying all requirements of the PACE program within the initial enrollment capacity constraints prior to accommodating increased enrollment. We also appreciate the comment regarding the timing of the first review during the trial period. We are committed to conducting timely annual reviews during each contract year of the PO's trial period. We will continue to

schedule reviews as expeditiously as possible consistent with statutory and regulatory requirements for the PACE program.

After considering the comments, we are finalizing the changes to § 460.12 as proposed.

3. CMS Evaluation of Applications (§ 460.18)

Section 460.18 describes the information that CMS uses to evaluate an application under PACE; however, this does not take into account all the potential sources of information that may be a part of the evaluation process, including information used in the evaluation of applications submitted for a PO that seeks to expand its service area and/or add a new PACE center site. Currently, § 460.18(b) specifies that CMS will use information obtained through on-site visits conducted by CMS or the SAA. Section 460.18(c) provides that CMS will use information obtained by the SAA. As discussed earlier in this section, we proposed to revise our regulations to reflect that an application also must be submitted for a PO that seeks to expand its service area and/or add a new PACE center site. We explained in the proposed rule that in evaluating expansion applications, CMS may consider additional information beyond that contained in the application itself, information obtained through on-site visits, or information obtained through the SAA. For example, our review of a SAE application might include information obtained from financial reviews, as well as the results from ongoing monitoring visits. Therefore, we proposed to combine the language currently in § 460.18(b) and (c) in revised § 460.18(b) and delete § 460.18(c). The revised § 460.18(b) would state that CMS uses information obtained by CMS or the SAA through on-site visits or any other means. We noted that this change would take into account the additional information that we use to review any PACE application, including applications to expand a PO's service area or add a new PACE center site. We also proposed to make a conforming change to the introductory language in § 460.18 to reflect the review of expansion applications, by deleting ''for approval as a PACE organization.''

A discussion of the comments we received on the proposed changes to the application evaluation requirements, and our responses to those comments, appears below.

Comment: One commenter noted the proposed modification would enable CMS to use information obtained by CMS or the SAA through on-site visits or any other means in order to evaluate a PACE application, and requested clarification regarding what encompasses ''any other means.''

Response: As we stated in the proposed rule (81 FR 54671), it is our intent to capture all the potential sources of information that may be part of the application evaluation process. Information obtained by ''any other means'' may include, but is not limited to, information obtained through the SAA, from financial reviews, or from ongoing monitoring visits.

We are finalizing the modifications to § 460.18 as proposed.

4. Notice of CMS Determination (§ 460.20)

Section 460.20 describes requirements for CMS to notify PACE applicants of the status of PACE applications. Currently, § 460.20 only specifies the requirements for CMS determination of applications submitted by entities seeking to become POs. As previously discussed in this section, we proposed to amend the regulations in subpart B to include, in addition to requirements for applications from entities seeking to become POs, requirements for applications submitted by existing POs for service area and/or PACE center site expansions. In conjunction with that proposal, we proposed changes to § 460.20 to also include specific language regarding the notification requirements for CMS determination of applications to expand a PO's service area and/or to add a new PACE center.

As we explained in the proposed rule, the current requirements in § 460.20 implement sections 1894(e)(8) and 1934(e)(8) of the Act, which require that an application for PO status be deemed approved unless the Secretary, within 90 days after the date of the submission of the application to the Secretary, either denies such request in writing or informs the applicant in writing with respect to any additional information that is needed in order to make a final determination with respect to the application. The Act further states that, after the date of receipt of any additional requested information from the applicant, the application must be deemed approved unless the Secretary, within 90 days of such date, denies such request.

While the Act requires that CMS provide notice to entities seeking to become POs of its determination within 90 days, the Act does not set out requirements for applications submitted by existing POs to expand their service area and/or to add a new PACE center site. We have published expansion application requirements in Chapter 17 of the PACE manual, available at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019036.html.* Under that guidance, a PO is required to submit an expansion application when the PO is seeking to (1) expand its geographic service area; (2) add a new PACE center; or (3) expand its geographic service area and add a new PACE center.

The guidance provides that, when a PO submits an expansion application to expand its geographical service area without building additional sites, CMS has 45 days to request additional information from the PO, approve the application, or deny the application. Similarly, when a PO submits an expansion application to add a new PACE center in the existing service area, CMS has 45 days to request additional information from the PO, approve the application, or deny the application. In these scenarios, if CMS requests additional information and the applicant provides the requested information, CMS has an additional 45 days to review and either approve or deny the expansion application. The second 45-day review period in this scenario only commences once CMS has received all of the additional requested material. If the applicant submits additional information per CMS' request, but CMS determines that there is still outstanding information requested from the applicant, CMS notifies the applicant and the additional 45-day review period does not begin until all requested information is received. Once we have received all of the requested information, CMS sends a letter to the applicant indicating that the second 45-day review period has commenced.

In the third scenario, when a PO submits an expansion application to expand its geographic service area and open a new PACE center site, CMS has 90 days to request additional information from the PO, approve the application, or deny the application. In this scenario, if CMS requests additional information and the PO provides the requested information, CMS has an additional 90 days to review and either approve or deny the expansion application. The second 90-day review period in this scenario only commences once CMS has received all of the additional requested material. If the applicant submits additional information per CMS' request, but CMS determines that there is still outstanding information requested from the applicant, CMS notifies the applicant and the additional 90-day review period does not begin until all requested

information is received. Once CMS has received all of the requested information, CMS sends a letter to the applicant indicating that the second 90-day review period has commenced.

We proposed to codify our current subregulatory requirements for notifying POs of CMS determinations regarding service area and PACE center site expansion applications so the regulations include all of the relevant application timing requirements. Specifically, we proposed to amend § 460.20(a) to make it clear that the notice of CMS determination applies to all three types of applications listed in proposed § 460.10(a), and that the 90-day time limit applies, except for applications to expand the service area or add a new PACE center site.

First, we proposed to delete § 460.20(a)(3) and revise § 460.20(b). Currently, § 460.20(a) states that CMS will approve or deny, or request additional information on, a ''complete application'' within 90 days after submission of the application. We explained in the proposed rule that we believe it is confusing to state that an application is complete if we are requesting additional information. Therefore, we proposed to delete § 460.20(a)(3), which is the provision that describes CMS requesting additional information needed to make a final determination, and we proposed to revise § 460.20(b) to state that an application is only considered complete when CMS receives all information necessary to make a determination regarding approval or denial. We noted that we would not consider the application complete without the required state assurance. We also proposed to revise § 460.20(a) to specify that the time limit for CMS notification of determination is 45 days for expansion applications where a PO seeks to expand its service area or add a new PACE center.

Next, we proposed that § 460.20(b) through (d) be redesignated as § 460.20(c) through (e) and revised as follows. We proposed to revise redesignated § 460.20(c) to describe the process if CMS determines that the application is not complete because it does not include sufficient information for CMS to make a determination. Specifically, CMS would inform the entity that the application is not complete and request the additional information, and within 90 days (or 45 days for a service area or new PACE center expansion application) of CMS receiving all requested information from the entity, CMS would approve the application or deny it and notify the entity in writing of the basis of the denial and the process for requesting reconsideration of the denial. We explained in the proposed rule that we proposed these changes because it is not possible for CMS to make an informed decision to approve or deny an application in situations where we do not have all of the pertinent information. We stated we would consider the SRR, which SAAs conduct to determine the PO's readiness to administer the PACE program and enroll participants, as information necessary to make our final determination and would request that the SRR be submitted in all applicable requests for additional information if we did not already have this information. We further noted that, if more than 6 months elapse between the date of submission of the application and the response to CMS' request for additional information, the entity is required to update the application to provide the most current information and materials related to the application; otherwise, we would consider the application incomplete. We proposed to revise § 460.20(c) accordingly.

Section 460.20(b), which we proposed to redesignate as § 460.20(c), currently outlines the requirements for POs when CMS requests from an entity additional information needed to make an application determination. As noted previously, we proposed to amend the language in this provision to address the different time limits for expansion applications. We also proposed to amend the language to specify that the time limits in § 460.20(a) do not begin until CMS receives all requested information and the application is complete. As we explained in the proposed rule, with the changes to § 460.20(a) and the addition of § 460.20(b), it would no longer be necessary to describe CMS' review process after all requested information has been received; thus, we proposed to remove § 460.20(b)(1) and (2).

Section 460.20(c), which we proposed to redesignate as § 460.20(d), currently implements sections 1894(e)(8) and 1934(e)(8) of the Act and provides that an application for PO status will be deemed approved if CMS fails to act on it within 90 days of the date the application is submitted or the date CMS receives all requested additional information. We proposed to amend this language to specify deemed approval will occur if CMS fails to act after the later of those dates, and that the provisions relating to deemed approval only apply to applications to become a PO, not expansion applications from existing POs. We stated in the proposed rule that this revision is necessary because, as described previously, we proposed to address expansion applications in the regulations, and we wanted to make it clear that only initial applications will be deemed approved if CMS fails to act on them within the required time period. As previously noted, the PACE statutes do not set out requirements for applications submitted by existing POs to expand their service area and/or to add a new PACE center site. We explained in the proposed rule that CMS does not currently employ ''deemed approval'' for expansion applications, and we noted we do not believe there is any reason to do so for these applications at this time. We further proposed to amend this language by specifying that the 90-day period commences after CMS has received a ''complete'' application, as this is consistent with the amendments to § 460.20(a) and § 460.20(b).

Finally, § 460.20(d) currently states that for purposes of the 90-day time limit described in this section, the date that an application is submitted to CMS is the date on which the application is delivered to the address designated by CMS. We proposed to redesignate § 460.20(d) as § 460.20(e), and revise this paragraph to refer to the time limits described in this section to include applications for service area expansions or new PACE center sites.

A discussion of the comments we received on the proposed changes to the CMS notice of determination requirements, and our responses to those comments, appears below.

Comment: Commenters questioned the necessity of the proposed provision that would require PACE applicants to update their applications if more than 6 months elapse between the date of initial submission of the application and the entity's response to the CMS request for additional information. Commenters also questioned whether CMS was proposing to require the applicant to withdraw its application and resubmit an entirely new application, or if CMS would permit less burdensome and timelier ways to update the existing application through submission of additional information. Commenters recommended the latter approach, and suggested allowing 12 months, as opposed to 6 months, to elapse between the date of application submission and the entity's response to the request for additional information before the entity is required to update its application. Commenters also recommended that the submission of additional information not be subject to CMS' quarterly submission timeframes for applications.

Response: After careful consideration of the comments, we have reconsidered

the timeframe that would require an update to the application. We agree with commenters that there may be valid reasons for delay in responding to our request for additional information (for example, unexpected delays in construction or licensing of the PACE center, or timing of the SRR); therefore, we accept the recommendation made by commenters and will specify that if more than 12 months, instead of 6 months, elapse between the date of initial submission of the application and the entity's response to our request for additional information, the entity must update the application with the most current information and materials related to the application. This means that, in addition to addressing the additional information requested by us, the applicant must submit all other application-specific documentation that may have changed during the interim 12-month period. We note that, depending on the nature of those changes and updates, there may be circumstances in which the applicant will be required to submit a completely new application; for example, if there is a change in the legal entity that is applying to become a PO.

With respect to commenters' recommendation that the submission of additional information not be subject to quarterly submission timeframes, we note that responses to a request for additional information are not limited to a quarterly submission cycle. While the application itself (initial or expansion) must be submitted on the established quarterly dates, information in response to a request for additional information may be submitted at any time.

Comment: We received comments in response to the proposed provision regarding deemed approval of initial applications. One commenter did not believe that an application should be deemed approved due to CMS' inability to review and act on an application within the required timeframes. This commenter believed that all documentation submitted to fulfill an application as complete must be reviewed and approved by CMS without any deemed approval. Other commenters noted that CMS, in the preamble to the proposed rule, stated that it does not believe it is necessary to allow deemed approval for expansion applications, as it has not done so in the past. Commenters requested that CMS reconsider this position and allow deemed approval of applications from POs seeking to expand a service area, with or without adding a new PACE center. While recognizing that CMS has always acted on expansion applications within the timeframes required for initial applications, the commenters stated there is no reason to preclude deemed approval if CMS is unable to act on an expansion application in a timely manner for some reason.

One commenter stated that, in cases in which the deemed approval requirement is triggered, it is still necessary for CMS to issue confirmation that deemed approval took place in order to effectively track the status of the review process.

Response: Sections 1894(e)(8) and 1934(e)(8) of the Act require an application for PO status to be deemed approved unless the Secretary, within 90 days after the date of the submission of the application to the Secretary, either denies the request in writing or informs the applicant in writing with respect to any additional information that is needed to make a final determination. The Act further states that, after the date of receipt of any additional requested information from the applicant, the application must be deemed approved unless the Secretary, within 90 days of such date, denies such request. As we noted in the proposed rule, the PACE statutes do not specifically address expansion applications. As such, we proposed to specify in redesignated § 460.20(d) that the deemed approval requirement only applies to entities that submit an initial application. As stated in the proposed rule, we do not currently employ deemed approval for expansion applications and we do not believe there is valid reason to employ deemed approval for expansion applications at this time. We appreciate the recognition from commenters that we have, to date, rendered decisions regarding expansion applications within the timeframes required for initial applications; however, we do not want to be in a position in which a deeming process supersedes our ability to make thoughtful, proactive decisions regarding these expansion applications. Therefore, we are finalizing our proposal that the deemed approval requirement will not apply to expansion applications.

Regarding the comment that we must issue confirmation that an application has been deemed approved, we note that the automated PACE application system sends communications to applicants regarding the status of their application, and applicants would receive formal notification of any deemed approval in the approval letter that accompanies the applicant's executed PACE program agreement. In light of these communications, we do not believe separate CMS confirmation of deemed approval is necessary. However, based on the input received, we will consider modifications to our auto-generated communications to include additional information regarding timeframes for review.

Comment: One commenter explained the process one specific SAA must undergo in order to effectuate service area expansions and expansions involving new PACE centers, and suggested that CMS and the SAA consider ways to better coordinate and shorten the timeframes for approval of expansion applications. The commenter noted that CMS has 90 days after submission of the SRR to make a determination with regard to the application and questioned whether it would be possible to allow a PACE center to open immediately upon receipt of the completed SRR.

Response: We note that our review timeframe may be 45 or 90 days depending on the type of expansion application. While we seek to review expansion applications as expeditiously as possible, adequate time must be afforded to us to review all aspects of an application, including responses to any requests for additional information, as well as the SRR. As a party to the PACE program agreement, we must carefully review all elements of the application, including the SRR, and therefore, would not consider allowing a PACE center to begin operations immediately upon our receipt of the SRR. We note that, even after we receive the SRR and any information submitted in response to a request for additional information and we determine the application is approvable, we require additional time to amend and execute the PACE program agreement and ensure that proper steps have been taken to accommodate enrollment of participants and payment to the PO. Within the past year, we have significantly expedited the effective date for approvals of expansion applications, often making them effective upon the date of approval of the expansion application.

After carefully considering all comments, we are finalizing § 460.20 as proposed, with one modification. Under § 460.20(c)(2), an entity will be required to update its application if more than 12 months, as opposed to 6 months, elapse between the date of initial application submission and the entity's response to the CMS request for additional information.

5. Service Area Designation (§ 460.22)

As discussed in section III.C.2. of this final rule, we proposed to move the content of § 460.22, in its entirety but with a few revisions, to § 460.12(c).

Therefore, we proposed to delete § 460.22.

A discussion of the comments we received on this proposed change, and our responses to those comments, appears below.

Comment: One commenter questioned whether the proposed removal of § 460.22 means that zip code expansions will no longer be required, and if so, whether expansion information will be documented as part of PACE program agreement updates.

Response: We assume the commenter is questioning whether expansion applications from POs that seek to expand their approved geographic service area will no longer be required. We address application requirements specific to service area expansions in section III.C.2. of this final rule. However, we wish to clarify that we proposed to move the current content of § 460.22 to § 460.12(c), which is why we proposed to delete § 460.22. We note that a description of the service area will still be required as part of the application, in accordance with existing requirements and documented as part of Appendix C of the PACE program agreement.

Comment: A few commenters addressed the provision that states CMS, in consultation with the SAA, may exclude from designation an area that is already covered under another PACE program agreement to avoid unnecessary duplication of services and avoid impairing the financial and service viability of an existing program. One commenter expressed support for this provision. Another commenter expressed appreciation of CMS' goal and emphasized the word ''may'' in this provision, as some degree of competition between PACE programs in the same geographic area may be useful to ensure adherence to minimum quality standards and encourage the provision of quality services.

Response: We note that this provision is based on sections 1894(e)(2)(B) and 1934(e)(2)(B) of the Act, and it is not a new provision or revision to an existing provision. Rather, we are simply moving the provision, in its current form, from § 460.22(b) to § 460.12(c)(2). As a result, we proposed to delete § 460.22(b). After considering the comments, we are finalizing this change as proposed.

Comment: One commenter expressed support for current provisions that require clearly-defined geographic service areas for both initial and expansion applications. The commenter also expressed the need to ensure flexibility regarding the designation of service areas. The commenter noted that traditional reliance on boundaries defined by county lines or Core Based Statistical Areas (CBSA) may prove arbitrary in terms of reflecting the actual distribution of a population in need of services. The commenter also noted innovations such as telehealth are redefining traditional concepts of a service area, in both rural and urban settings. The commenter stated that flexibility in defining service areas enhances the ability to target PACE services to populations that could support and benefit from coverage by more than one PO; for example, there could be situations in which a new PO seeking to enter a market is willing to introduce innovation or serve a specialized population that an existing PO is unable or unwilling to match.

Response: We note that § 460.32(a)(1) allows the service area of a PO to be identified by county, zip code and other means. Therefore, applicants are not necessarily bound by traditional geographic designations. With respect to the comment regarding innovative service delivery approaches that could be considered when defining service areas, we appreciate this input and may consider it as part of subregulatory guidance or rulemaking in the future.

Comment: One commenter acknowledged that both the current and proposed regulations require an applicant entity to identify the service area the PACE program wishes to serve, noting, specifically, that CMS, in consultation with SAAs, may exclude an area that is already being served by another PACE program agreement. One commenter noted that Tribal Health Programs (THPs) have a unique relationship with the American Indian/Alaska Native (AI/AN) beneficiaries they are contracted to serve. Specifically, AI/AN beneficiaries have the ability under Medicaid to receive services from a THP, even when the AI/AN is enrolled in a managed care product, and the THP has the right to receive reimbursement for services provided. Therefore, the commenter requested that CMS specify an exception to the service area designation requirement to allow THPs to identify the Indian Health Service (IHS) Service Area in their application, even if a non-Indian PACE program already exists in all or part of that IHS Service Area.

Response: We interpret the comment to be specific to a THP that may apply to offer a PACE program. We note that, under § 460.32(a)(1), a service area may be defined by county, zip code and certain other means including tribal jurisdictional area, as applicable, and this is explicitly stated in the PACE application. We further note that the regulatory language currently in § 460.22(b) states that CMS, in consultation with the SAA, may exclude from designation an area that is already covered under another PACE program agreement to avoid any unnecessary duplication of services and avoid impairing the financial and service viability of an existing program. Whether another PO is currently serving a designated service area is therefore a consideration in the potential exclusion of that area, not an absolute requirement for exclusion.

After considering the comments, we are finalizing the changes to § 460.22 as proposed.

6. Submission and Evaluation of Waiver Requests (§ 460.26)

Section 460.26 sets forth the process for submitting and evaluating waiver requests. We proposed to revise current § 460.26(a)(1) and (2) so that § 460.26(a)(1) would state that a PO, or an entity submitting an application to become a PO, must submit its waiver request through the SAA for initial review. Paragraph (a)(1) would also specify that the SAA forwards waiver requests to CMS along with any concerns or conditions regarding the waiver. We proposed that section 460.26(a)(2) would state that entities submitting an application to become a PO may submit a waiver request as a document separate from the application or in conjunction with and at the same time as the application. While we did not propose any policy changes in the proposed rule, we stated that we believed these changes would make the requirements for submission of the waiver request more concise and clear. We noted that we plan to provide additional detail on this part of the process in subregulatory guidance.

Section 460.26(b) states that CMS evaluates a waiver request from a PO on the basis of certain information. We proposed to add ''or PACE applicant'' after ''PACE organization'' because a waiver request can be submitted by an existing PO or a PACE applicant (an entity that has applied to be a PO but is not yet a PO, or a PO applying to expand its service area and/or add a new PACE center site).

A discussion of the comments we received on the proposed changes to the waiver process requirements, and our responses to those comments, appears below.

Comment: We received many comments in support of the proposed changes to the waiver submission process language. Commenters also requested clarification on whether waiver requests can be submitted as part of an entity's initial application or

whether the waiver requests have to be submitted to CMS by the SAA.

Response: Under our current process, entities submitting an application to become a PO may submit a waiver request either as a separate document or in conjunction with their initial application. We are adding language to § 460.26 to clarify that an applicant may submit a separate waiver request through the SAA or the applicant may submit a waiver request in conjunction with and at the same time as the initial application, now that the application submission process is automated. As previously required, a waiver request submitted with an initial application must include a letter from the SAA indicating the State's concurrence, concerns, or conditions related to the waiver request. We note that our review of any waiver requests submitted in conjunction with the initial application will be reviewed in accordance with the 90-day review period for waiver requests in § 460.28. We are making one additional change to § 460.26(a)(1) to refer to the SAA's concurrence, as well as any concerns or conditions, regarding the waiver, to align that provision with the proposed requirement in § 460.26(a)(2) for waiver requests submitted in conjunction with initial applications.

Comment: One commenter expressed concern that we have not included provisions for broader waiver types that address a systematic issue and noted the example of hiring social workers with a bachelor's degree instead of a master's degree in areas where it is difficult to hire a Master's-level social worker. The commenter recommended that POs be afforded the ability to request a blanket waiver, meaning no limitation on the effective period of the waiver, to allow targeted flexibility for a specific, documented purpose, such as in the example cited. In the absence of additional flexibilities, the commenter stated that POs may have to submit multiple waiver requests over time to address the same type of flexibility, which is a time-consuming and costly process for POs.

Response: With the exception of the requirements specified in § 460.26(c), POs have broad latitude to request waivers to address localized, systematic issues on a long-term basis, such as the example cited by the commenter, as long as all waiver requirements are met. In addition, we believe the revisions we are making to the regulations in this final rule will result in fewer waiver requests. Specifically, the additional flexibilities we are providing, such as the changes to the IDT requirements at § 460.102, will permit POs to operate their programs with these flexibilities and no longer require POs to request waivers of those requirements. For example, we are finalizing changes to allow community-based physicians to serve as the primary care provider on the IDT. Prior to these regulatory changes, POs would have had to request a waiver of this requirement in order for a community-based physician to function in the role of the primary care physician on the IDT.

Comment: One commenter requested that when CMS is seeking to deny a waiver request that the SAA reviewed and supports, there should be provisions in place for consultation with the state before CMS makes a final determination. The commenter acknowledged this practice is already in place; however, the commenter would like it to be codified in the regulations to ensure consistency.

Response: We consult with the SAA on all waiver requests and do not believe it is necessary to codify this practice in our regulations. We intend to clarify this practice in future guidance.

After considering the comments, we are finalizing the proposed changes to § 460.26 in part, with modifications to clarify that an applicant may submit a separate waiver request through the SAA, per the quarterly deadlines, or the applicant may submit a waiver request in conjunction with and at the same time as the initial application, and a change to § 460.26(a)(1) to refer to the SAA's concurrence, as well as any concerns or conditions, regarding the waiver.

7. Notice of CMS Determination on Waiver Requests (§ 460.28)

Section 460.28 discusses the timeframes for CMS determination and notification regarding approval or denial of waiver requests. As we explained in the proposed rule, we established this section to implement section 903 of BIPA, which provides in relevant part that the Secretary shall approve or deny a request for a modification or a waiver not later than 90 days after the date the Secretary receives the request. We proposed to retain most of the language in current § 460.28(a), but to specify that the 90-day time limit starts after CMS receives a complete waiver request. We discuss the need for a complete waiver request in subsequent paragraphs. In § 460.28(a), we proposed to revise the heading to ''General,'' delete the reference to a denial being ''in writing,'' and state that CMS will take action on the complete waiver request in the form and manner specified by CMS. We proposed these changes to reflect how we provide notification, whether electronically or in another format. We noted in the proposed rule that CMS would not only provide notification verbally. We proposed to redesignate § 460.28(a)(2) as new § 460.28(a)(3).

We proposed to add a new § 460.28(a)(2) to address conditional approval of a waiver request from a PACE applicant when the application is still pending. We explained in the proposed rule that under CMS' current process, a PACE applicant may request a waiver while its application is still pending and receive either a denial of the waiver request or a conditional approval of the waiver request. The approval of the waiver request is conditioned on the approval of the application. CMS will only issue conditional approvals to entities with pending applications. We noted that issuing a conditional approval enables CMS to adhere to the BIPA 90-day timeframe for making a determination with respect to a waiver request in situations where an application is still under review. Waiver requests that are not associated with a pending application either receive an approval or denial.

In addition, we proposed to remove the language in § 460.28(b) regarding the date of receipt of the waiver, because we believed the proposed changes to § 460.28(a) and (b) make it clear that the 90-day clock will start on the day CMS receives a complete waiver request. We also proposed to change current paragraph (c)(1) regarding deemed approval of a waiver request to refer to CMS failing to act within 90 days of receipt of a complete waiver request, and redesignate it as paragraph (c). We stated that CMS will notify POs to confirm receipt of ''complete'' waiver requests.

We proposed new language in § 460.28(b) regarding additional information requests for waivers. We explained in the proposed rule that unlike sections 1894(e)(8) and 1934(e)(8) of the Act, which give CMS 90 days to request additional information from entities applying to become POs, section 903 of BIPA does not explicitly impose a time limit for CMS to request additional information that is necessary to make a determination on a waiver request. In the 2006 final rule, we stated that there is ''no statutory authority to stop the 90-day clock if additional information is necessary to make a determination on a waiver request.'' (71 FR 71255). We noted in the proposed rule that although we cannot stop the clock, we believe the statute can be read to start the 90-day clock upon CMS' receipt of a complete waiver request. Therefore, we proposed

in new paragraph (b) that a waiver request is complete when CMS receives all information necessary for CMS to make a determination regarding approval or denial. We stated that if CMS determines the waiver request is not complete, CMS would request additional information needed to make a determination. The 90-day clock would start when CMS receives the complete waiver request. We noted that we proposed these changes because it is not possible to make an informed decision to approve or deny a request for a waiver in situations where we do not have all of the pertinent information. We further stated that we believed this change would reduce the administrative burden on CMS, as well as the POs because, currently, CMS denies incomplete waiver requests and POs must resubmit new waiver requests that include the missing information. Under the process we proposed, CMS and the PO would work together to ensure that the request includes all necessary information, which should alleviate the need to resubmit a waiver request.

We explained in the proposed rule that this is similar to the treatment of PACE applications, and we believed consistency in review procedures would be helpful to all parties involved. We also noted that approval of a waiver associated with a PACE application is contingent upon the approval of that PACE application because there is nothing to waive if there is no PACE program. Accordingly, waivers that are submitted for review in conjunction with a PACE application or while a PACE application is being reviewed would only be approved if that application is approved. As previously discussed, we proposed to add a new § 460.28(a)(2) that provides for conditional approval for entities with a pending application to become a PO.

Currently, § 460.28(c)(2) allows CMS to withdraw its approval of a waiver for good cause. We proposed to redesignate this provision as (d)(1) and amend it to provide that CMS ''in consultation with the'' SAA may withdraw approval of a waiver request for good cause. We proposed to add this language because any significant change to the PACE program agreement, which includes waivers, should be made in consultation with the SAA because the SAA also is a signatory of the agreement. We proposed in § 460.28(d)(2) that, if the waiver approval is withdrawn, CMS must notify the PO or PACE applicant and the SAA that approval of a waiver has been withdrawn and specify the reason for withdrawal and the effective date of the withdrawal in the notice. We noted that currently, while the regulation enables CMS to withdraw an approval of a waiver request, it does not require that we notify the PO or PACE applicant and the SAA of the withdrawal, the reason for withdrawal, or the date when the withdrawal would be effective. We stated that we believe this information is critical to the PO or PACE applicant and the SAA because it likely would require a change in operation of the PO or could change how an applicant would operate a PO if its application is approved.

A discussion of the comments we received on the waiver determination and notification process, and our responses to those comments, appears below.

Comment: Some commenters requested that we implement a 30-day timeframe to determine if a waiver request is complete and then reduce the 90-day timeframe for review to 60 days. Commenters also expressed that as CMS adds additional flexibilities to the PACE regulations, there may be fewer waiver requests, and some of the commenters requested that CMS reduce the 90-day review period to 60 days.

Response: We appreciate the commenters' suggestions. We note that if we consider the waiver request we receive to be complete, the 90-day review timeframe would have started upon receipt of that request. Consequently, it is in our interest, as well as the PO's interest, for us to make this completeness determination promptly, and we do not believe it is necessary to implement a shorter timeframe for making this determination. While we agree with commenters that we anticipate receiving fewer waiver requests in the future due to the additional flexibilities provided in this final rule, we note that the length of time we need to review a waiver request will not be affected by the number of requests received.

Comment: One commenter described the process one specific SAA must undergo in order to effectuate service area expansions and expansions involving new PACE centers and suggested that CMS and the SAA consider ways to better coordinate and shorten the timeframes for approval of PO waivers. The commenter noted that CMS has 90 days after submission to complete the review.

Response: Section 903 of BIPA provides that the Secretary must approve or deny a waiver request not later than 90 days after receiving the request, and that is the timeframe we established in § 460.28. At this time, we are not in a position to commit to a shorter review period than the established 90-day review period. While we seek to review waivers as expeditiously as possible, adequate time must be afforded to review all aspects of the waiver, including responses to any requests for additional information.

After careful consideration of the comments received, we are finalizing this proposal without modification.

D. Subpart C—PACE Program Agreement

1. Content and Terms of PACE Program Agreement (§ 460.32)

Section 460.32 specifies the required and optional content of a PACE program agreement. Under § 460.32(a)(12), a PACE program agreement must contain information about the Medicaid capitation rate and the methodology used to calculate the Medicare capitation rate. This requirement is based on sections 1934(d)(2) and 1894(d)(2) of the Act, which provide that the Medicaid capitation amount and the Medicare capitation amount, respectively, to be applied for a PO for a contract year must be an amount specified in the PACE program agreement for the year.

Section 460.32(a)(12) and § 460.180(b) require the PACE program agreement to specify the methodology used to calculate the Medicare capitation rate, as opposed to the actual rate. The PACE Medicare rate is based on Part A and B payment rates established for purposes of payments to Medicare Advantage organizations and is subject to certain other adjustments (see § 460.180). For the Medicaid capitation rate, however, our current regulations require the PACE program agreement to specify the actual amount negotiated between the POs and the SAA (see § 460.32(a)(12) and § 460.182(b)).

As states are moving toward more managed care delivery systems for the long term care population, some states are redesigning their methodologies for developing PACE Medicaid capitation rates to more closely align with these other managed care delivery systems. Some of the new methodologies result in Medicaid payment variations based on factors such as frailty adjustments and performance incentive payments. Additionally, because many states update their PACE Medicaid capitation rates annually based on the state fiscal year, there are operational challenges associated with updating the PACE program agreement appendices to reflect changes to the Medicaid rates because they are not necessarily updated consistent with a PACE program agreement's contract year. As a result, we stated in the proposed rule that we

believed it is not always practical to include the actual Medicaid capitation rates in the PACE program agreement. Therefore, we proposed to amend § 460.32(a)(12) to require that the program agreement include the Medicaid capitation rates or Medicaid payment rate methodology, as well as the methodology used to calculate the Medicare capitation rate. Medicaid capitation rates are developed and updated by the states (in negotiation with the POs) and approved by CMS. Operationally, states submit documentation to CMS to support their proposed PACE Medicaid capitation rates. CMS reviews the documentation to ensure the rates are in compliance with the requirements of § 460.182, and provides the state with written approval of the rates. The Medicaid capitation rates are then communicated to the POs by the state in writing.

We also solicited comments regarding other modifications we might make to the required content of the PACE program agreement, specifically, those cited at § 460.32(a) and § 460.182(d). We specifically requested comments regarding the need for capturing the level of detail currently required within the agreement itself, along with updated information as may be necessary throughout the contract period. Much of the required program agreement content relates to operational components of the PO's program. We explained that our expectation is that POs regularly review and update this information, particularly as it relates to policies and procedures, to ensure its business practices are current, compliant with regulation and guidance, and consistently employed. We solicited comments on whether specific policies and procedures, and other existing requirements, should continue to be part of the PACE program agreement.

A discussion of the comments we received on the PACE program agreement requirements, and our responses to those comments, appears below.

Comment: A commenter requested that CMS modify the PACE regulations to allow a PO to enter into a two-way agreement with CMS to provide services to Medicare beneficiaries in states that do not establish PACE as a State option under Medicaid. In these situations, the commenter recommended that CMS require the potential PO to submit the application with a statement by the state regarding which, if any, of the state functions the state is willing to perform; for example, the SRR, nursing home level of care determination, etc.

Response: We did not propose any changes to the current PACE program agreement between a PO, CMS and the SAA for the operation of a PACE program. Therefore, we consider this comment to be outside the scope of this rule. However, we note that in the 1999 IFC and the 2006 final rule, we articulated, in great detail, requirements an entity must meet in order to be approved as a PO and the basis for those requirements, including the requirement for a tripartite agreement and rationale for requiring that POs participate in both Medicare and Medicaid (64 FR 66237; 71 FR 71251). As we stated in those rules, the authorizing PACE statutes (sections 1894 and 1934 of the Act) envision active collaboration between federal and state governments in the administration of the PACE program. As described in the 1999 IFC and 2006 final rule, the SAA is responsible for a wide array of functions related to the operations of a PACE program, including: (1) The SRR conducted as part of activities to approve an entity as a PO; (2) assessment of potential participants to ensure nursing facility level of care requirements are satisfied; and (3) cooperation with CMS in the oversight of the PACE program (which includes authority to terminate a PACE program agreement for cause, as a party to the tripartite agreement), among other key activities. As we stated in those rules, it is our belief that a state which has not elected PACE as an optional service would likely be ill-prepared or even unable to perform these critical activities. We concluded in those rules that a Medicare-only program could not meet the fundamental concept of an all-inclusive, integrated, capitated, full-risk program. Our position today has not changed; we continue to believe that the rationale for structuring the PACE program as we have is valid and appropriate.

Comment: A number of commenters expressed support for CMS' proposal to modify the current requirement in § 460.32(a)(12) that the Medicaid capitation rate be included in the PACE program agreement. Commenters noted that the proposed change would allow for either the Medicaid capitation rate(s) or the Medicaid payment rate methodology to be included in the PACE program agreement. These commenters stated that the proposed approach effectively streamlines updates to the PACE program agreements and provides states the flexibility to adapt to potential payment rate changes and variations.

Response: We thank the commenters for their support.

Comment: One commenter recommended that the final rule provide clarity on the level of detail expected in the PACE program agreement for states that opt to include the Medicaid rate methodology. The commenter noted that states already undergo a comprehensive review of their PACE Medicaid rate methodology by CMS annually. Therefore, commenters requested that CMS allow a more general methodology description to be allowed in the PACE program agreement to further the flexibility discussed in the proposed rule and recognize the extensive methodology review process already taking place. The commenter further noted this would avoid the burden of frequent updates to the PACE program agreement while leveraging, rather than duplicating, the comprehensive Medicaid rate review process that CMS already undertakes. The commenter also requested that CMS clarify the timeframe in which a state must update the actual Medicaid capitation rate in the PACE program agreement if the state elects to include the Medicaid rate instead of the methodology.

Another commenter noted that the PACE Medicaid capitation methodology is complex and often confusing and that this change removes any incentive for SAAs to timely ''negotiate'' the monthly capitation amount with POs and produce rate schedules. In addition, the commenter urged CMS to clarify the negotiation requirement to establish the monthly Medicaid capitation amounts. The commenter indicated that in one state, Medicaid rates are set using an actuarial formula, which takes into account regulatory requirements and the state's priorities, which effectively precludes POs from annually negotiating with the SAA. Instead of focusing on regulatory revisions to reflect the status quo, the commenter urged CMS to consider including language to affirmatively require timely Medicaid rate setting for the PACE program and buttress the ability of POs to negotiate rates.

Response: We are not specifying the level of detail that the state must include in the PACE program agreement to describe the state's methodology for Medicaid capitation rates. The state must provide enough detail about the Medicaid payment rate methodology to ensure it is in compliance with requirements of § 460.182, but the state will have flexibility in the level of detail that is provided. In December 2015, we released guidance to states regarding the Medicaid rate setting process that outlines submission and timeframe expectations related to development and approval of Medicaid capitation rates under PACE. The PACE Medicaid

Capitation Rate Setting Guide was developed as a resource for states and it includes critical elements of rate setting that incorporate both the state development of the amount that would otherwise been paid if individuals were not enrolled in PACE, and development of the PACE rates. The guide can be found at *https://www.medicaid.gov/medicaid/ltss/downloads/integrating-care/pace-medicaid-capitation-rate-setting-guide.pdf.* We expect to update the guide in the future to provide more detail and clarification in certain areas as necessary.

Additionally, while we do review the state Medicaid rate documentation to ensure that the PACE rates meet all requirements under § 460.182, including that the monthly capitation amount is less than the amount that would otherwise have paid under the state plan if the participants were not enrolled under the PACE program, the state has flexibility in establishing the rate as long as it meets those requirements, which includes the flexibility of negotiating with POs. The process for negotiation of the monthly capitation payment amount between the PO and the SAA varies by state. We do not require a specific process for negotiation as long as the rates meet the requirements of § 460.182(b).

Comment: One commenter encouraged CMS to engage with SAAs to determine which components of the PACE program agreement are necessary from the states' perspective. The commenter expressed support for efforts to remove detailed information that changes with some frequency, for example, administrative contacts that are available in CMS' HPMS. It is the commenter's expectation that the PACE program agreement would generally include high-level requirements as opposed to specific program policies and procedures.

Response: We appreciate the thoughtful comments and suggestions and will consider the feedback provided as part of possible future rulemaking.

Comment: One commenter noted that § 460.34 currently states: ''An agreement is effective for a contract year, but may be extended for additional contract years in the absence of a notice by a party to terminate.'' The commenter recommended this language be modified as follows: ''An agreement is effective for a contract year, but *shall* be extended for additional contract years in the absence of a notice by a party to terminate.''

Response: We did not propose any changes to the regulatory provision at § 460.34 regarding the duration of PACE program agreements. Therefore, we consider this recommendation to be beyond the scope of this regulation. However, we may consider this suggestion as part of possible future rulemaking. After considering the comments, we are finalizing the amendment to § 460.32(a)(12) as proposed.

E. Subpart D—Sanctions, Enforcement Actions, and Termination

1. Violations for Which CMS May Impose Sanctions (§ 460.40)

To support PACE program integrity and to protect PACE participants, we proposed to amend provisions related to enforcement actions we may take when POs fail to comply with the PACE program agreement and/or program requirements. Currently, § 460.50 identifies some causes for CMS or an SAA to terminate a PACE agreement. Provisions authorize terminating for cause in circumstances including, but not limited to, uncorrected failure to comply substantially with conditions of the PACE program or with the terms of the PACE agreement, and inability to ensure the health and safety of participants, such as the presence of deficiencies that CMS or the SAA determines cannot be corrected. As we explained in the proposed rule, while current regulations reflect CMS and the SAA's authority to terminate an organization in these circumstances, we believed that we needed to clarify our authority with respect to alternative enforcement actions in the form of sanctions or civil money penalties (CMPs).

We proposed adding a new provision to § 460.40, designated as paragraph (b), to allow CMS the discretion to take alternative actions in the form of sanctions or CMPs when we are authorized to terminate a PO's PACE program agreement. We noted in the proposed rule that, consistent with the authorities in sections 1894(e)(6)(B) and (f)(3) and sections 1934(e)(6)(B) and (f)(3) of the Act, this new provision would align the PACE enforcement structure with the enforcement structure that applies to the Medicare+Choice program, renamed, and hereinafter referred to, as the MA program. The MA program enforcement authorities in sections 1857(g)(3) and (4) of the Act allow CMS the discretion to take enforcement actions in the form of sanctions or CMPs when CMS is authorized to terminate the organization's contract. We proposed that this approach also be utilized in the PACE program, consistent with our statutory authority identified in sections 1894(e)(6)(B) and 1934(e)(6)(B) of the Act, and to promote consistency with the enforcement structure of the MA program. We stated that the change would give CMS the discretion to impose sanctions and CMPs on POs for continued noncompliance, in addition to our current authority to take the most extreme action of termination of the PACE program agreement. To add paragraph (b), we proposed to redesignate the introductory language in § 460.40 to paragraph (a) and redesignate paragraphs (a) through (i) to paragraphs (a)(1) through (a)(9).

2. Civil Money Penalties (§ 460.46)

Due to the redesignation of paragraphs in § 460.40, we also proposed to make technical, non-substantive changes to the citations in this section to reflect the substantive and technical changes discussed above. Specifically, we proposed to amend § 460.46(a)(1) by removing the reference ''§ 460.40(c) or (d)'' and adding in its place the reference ''§ 460.40(a)(3) or (4)''. We proposed to amend § 460.46(a)(2) by removing the reference ''§ 460.40(e)'' and adding in its place the reference ''§ 460.40(a)(5)''. We also proposed to amend § 460.46(a)(3) by removing the reference ''§ 460.40(f)(1)'' and adding in its place the reference ''§ 460.40(a)(6)(i)''. These changes reflect the new numbering of § 460.40 that was discussed previously.

Additionally, we proposed to revise § 460.46(a), in accordance with the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 Act) (Sec. 701 of Pub. L. 114–74). The 2015 Act requires agencies to adjust the civil money penalties annually for inflation. The Department of Health and Human Services will publish all of the Department's adjusted CMP amounts at 45 CFR part 102. To ensure transparency, we proposed revising § 460.46(a) to state that the penalty amounts are adjusted for inflation and citing to 42 CFR 1003.102.

The following is a summary of the public comments we received on the proposed provisions regarding sanctions, enforcement actions, and termination, and our responses to comments.

Comment: Commenters were supportive of our proposed revisions. A few commenters mentioned that allowing sanctions or CMPs to be taken prior to termination would help POs have time to correct identified issues of noncompliance. Other commenters, while supportive, cautioned CMS to consider the size and financial stability of POs prior to implementing a sanction or CMP, stating that a large CMP or enforcement action could effectively

drive a PO out of business. One commenter recommended that CMS perform a risk benefit analysis prior to implementing a sanction or CMP to ensure the benefit outweighed the potential risk.

Response: We agree with these commenters that revising the regulations to enable us to take enforcement actions other than termination will be beneficial to POs by allowing them time to correct deficiencies. We appreciate commenters concerns regarding the potential adverse impact of CMPs and sanctions on POs. We intend to use the new range of penalties in a manner that appropriately accounts for the size and structure of the PO subject to the enforcement action.

Comment: A few commenters referenced SAAs. One commenter requested clarification on how the SAA and CMS would work cooperatively on enforcement actions, and if the SAA would be informed prior to a sanction being placed on a PO. Another commenter requested that CMS modify the regulatory language in § 460.40(b) to say that either CMS or the SAA may take a sanction or CMP. The same commenter requested that any money collected from a CMP be split evenly between CMS and the state. Lastly, one commenter requested that we add a new paragraph (c) to the regulation that discusses a state's authority to take enforcement actions based on State laws and regulations.

Response: We are committed to maintaining a close partnership with SAAs in overseeing POs. When taking enforcement actions, we will notify the SAA prior to taking the action, as appropriate. However, we are not modifying the regulatory language in the new § 460.40(b) to address SAAs' ability to take sanctions or CMPs. This regulatory language is aligned with sections 1894(e)(6)(B) and 1934(e)(6)(B) of the Act, which do not address the state's ability to take an enforcement action or require consultation with the SAA before imposing sanctions or CMPs, and we believe that we should keep the language similar in this regulation. We are also not accepting the suggestion to add a new paragraph into the regulation to address a state's ability to use state laws and regulations to take its own enforcement actions. We do not believe this level of detail is needed, as nothing in this regulation would prevent a state from using its own legal authority to impose a state enforcement action on a PO. However, we encourage states to coordinate with us prior to taking any enforcement actions against POs based on state authority. Also, while we appreciate the commenter's request that we split CMP money between the states and CMS, we are not authorized to dictate where that money goes, and cannot make that change.

Comment: A few commenters, while supportive of the proposed modification to our enforcement provisions, stressed the importance of consistency in audits, especially if audit findings are used in enforcement actions against POs. One commenter questioned what the reference to ''continued non-compliance'' meant, and whether that could mean repeat audit findings.

Response: In the proposed rule, we discussed the regulations regarding termination of a PACE program agreement, and that one of the reasons for termination was ''continued non-compliance'' which is discussed in 42 CFR 460.50(b). In the proposed rule, we noted that our proposed expansion to our enforcement authority would allow us to take other enforcement actions, outside of termination, for continued non-compliance. We define continued non-compliance as any instance in which a PO has been made aware it is not in compliance with a regulation or requirement, and the PO has failed to correct that issue within a reasonable period of time, or has repeated uncorrected deficiencies. What will constitute a reasonable period of time for correction may depend on the severity of non-compliance noted by CMS or the SAA. We want to clarify that while continued non-compliance may be identified through repeat audit findings, audits would not be the only source of information to inform an enforcement action. Although continued non-compliance could be revealed through audits, it could also be discovered through routine account management monitoring, quality reporting, or any other avenue in which CMS or the SAA discovers these issues. However, audits are one of the ways we would measure continued non-compliance and we agree that audit consistency is very important. We continue to make process improvements to PACE audits, including utilizing a revised audit protocol, continuing to refine and update internal auditor tools, utilizing a national audit consistency team, and implementing intensive auditor training specific to PACE.

After considering public comments, we are finalizing the changes to §§ 460.40 and 460.46 as originally proposed with the following technical changes. First, in § 460.46, we are making a technical change to the citation in the proposed note from 45 CFR 1003.102 to 45 CFR part 102, and including the language regarding inflation in the regulatory text and not as a note as originally proposed. Second, in § 460.40, we are redesignating paragraph (j) that was established in the November 15, 2016 **Federal Register** (81 FR 80561) as part of the final rule entitled, ''Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements'' and later modified in the April 16, 2018 final 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'' (83 FR 16756), as paragraph (a)(10). Finally, we note that the proposed regulation text for § 460.40(a)(3) included language concerning the criteria for sanctions even though our intention was solely to redesignate the paragraph. Therefore, we are modifying the final rule to remove the language regarding discrimination on the basis of an individual's functional, cognitive or psychosocial status, which was inadvertently included, redesignate the paragraph, and restore the language that refers to discrimination in enrollment or disenrollment among Medicare beneficiaries or Medicaid beneficiaries, or both, who are eligible to enroll in a PACE program, on the basis of an individual's health status or need for health care services.

F. Subpart E—PACE Administrative Requirements

1. PACE Organizational Structure (§ 460.60)

Sections 1894(a)(3)(A)(i) and 1934(a)(3)(A)(i) of the Act require a PO to be (or be a distinct part of) a public entity or a private, nonprofit entity organized for charitable purposes under section 501(c)(3) of the Internal Revenue Code of 1986. We implemented these provisions in § 460.60(a), which provides that a PO must be, or be a distinct part of, either (1) an entity of city, county, state, or Tribal government or (2) a private, not-for-profit entity organized for charitable purposes under section 501(c)(3) of the Internal Revenue Code of 1986, and it may be a corporation, a subsidiary of a larger corporation, or a department of a corporation. In this discussion, we will

refer to all entities that meet this standard as not-for-profit entities.

Sections 1894(h) and 1934(h) of the Act direct the Secretary to waive the requirement that a PO be a not-for-profit entity in order to demonstrate the operation of a PO by private, for-profit entities. Section 4804(b) of the BBA of 1997 requires the Secretary to provide a report to Congress on the impact of the demonstration on quality and cost of services, including certain findings regarding the frailty level, access to care, and the quality of care of PACE participants enrolled with for-profit POs, as compared to not-for-profit POs. Section 4804(b)(2) of the BBA of 1997 requires the report to Congress to include findings on whether any of the following four statements is true with respect to the for-profit PACE demonstration:

- The number of covered lives enrolled with entities operating under demonstration project waivers under sections 1894(h) and 1934(h) of the Act is fewer than 800 (or such lesser number as the Secretary may find statistically sufficient to make determinations respecting findings described in the succeeding subparagraphs).
- The population enrolled with such entities is less frail than the population enrolled with other POs.
- Access to or quality of care for individuals enrolled with such entities is lower than such access or quality for individuals enrolled with other POs.
- The application of such section has resulted in an increase in expenditures under the Medicare or Medicaid programs above the expenditures that would have been made if such section did not apply. (We refer to these statements collectively as the BBA statements.)

Under sections 1894(a)(3)(B)(ii) and 1934(a)(3)(B)(ii) of the Act, after the date the report is submitted to Congress, the requirement that a PO be a not-for-profit entity will not apply unless the Secretary determines that any of the BBA statements are true.

In 2008, Mathematica Policy Research completed a study of the permanent not-for-profit POs.[5] An interim report to Congress based on this study was submitted in January 2009. At the time of the 2008 Mathematica study, no for-profit entities had enrolled in the PACE demonstration. Therefore, neither report assessed a for-profit PACE population nor did the interim report address the BBA statements.

From 2012 to 2013, Mathematica, under contract with CMS, conducted a study to address quality of and access to care for participants of for-profit POs, specifically focusing on the third BBA statement. The 2013 Mathematica report also included information that provided insight into the first and second BBA statements.[6] Based on the two Mathematica studies, HHS prepared and submitted the report to the Congress on May 19, 2015. A copy of the report to Congress is available at *https://innovation.cms.gov/Files/reports/RTC_For-Profit_PACE_Report_to_Congress_051915_Clean.pdf.*

As detailed in the report, HHS could not conclude that any of the four BBA statements were true. First, the number of covered lives enrolled with for-profit POs was not fewer than 800, and the sample size for the survey examining BBA statements two and three was large enough to make statistically significant determinations of differences. The report stated that HHS could not conclude that for-profit PACE participants are less frail than not-for-profit PACE participants. It also stated that HHS could not conclude that for-profit PACE participants experienced systematic adverse differences in quality of care or access to care as compared to not-for-profit PACE participants. Finally, expenditures were equal between for-profit and not-for-profit POs after controlling for beneficiary risk score, organization frailty score, and county rates, so there would not have been an increase in expenditures if participants in the for-profit POs had been enrolled with a not-for-profit PO.

Based on the findings in the report to Congress, we determined that under sections 1894(a)(3)(B) and 1934(a)(3)(B) of the Act, the requirement that a PO be a not-for profit entity would no longer apply after May 19, 2015 (the submission date of the report to Congress). Because the statutory not-for-profit restriction no longer applies, in the proposed rule, we proposed to remove the corresponding restriction in § 460.60(a) in its entirety. We also proposed to redesignate § 460.60(b), (c), and (d) as § 460.60(a), (b), and (c), respectively.

A discussion of the comments we received on the proposal to remove the not-for-profit restriction in § 460.60(a), and our responses to those comments, appears below.

Comment: Commenters expressed concerns about CMS allowing for-profit entities to be POs. Many commenters believed that although the evaluation of the for-profit PACE demonstration found no significant reasons to restrict PACE to not-for-profit entities, CMS should continue its evaluation to identify and better understand any potential differences driven by ownership by a for-profit entity and to ensure that regulatory oversight is applied uniformly to all POs as it pertains to service utilization, participant frailty and outcomes and costs and experience. Other commenters recommended CMS consider requiring all for-profit POs to meet a ratio of services to revenues, similar to the medical loss ratio requirements set forth in the final rule published in the May 6, 2016 **Federal Register** (81 FR 27498) entitled, ''Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability.'' One commenter recommended CMS consider continuing its evaluation for up to 3 years for the for-profit POs. Another commenter supported the change to allow for-profit entities to be POs.

Response: As a result of the findings in the May 19, 2015 report to Congress, sections 1894(a)(3)(B) and 1934(a)(3)(B) of the Act state that the requirement that a PO be a not-for-profit entity will no longer apply. The findings of the report did not suggest that we establish different requirements for POs based on their profit status, and we see no basis for applying a different set of requirements, such as medical loss ratio requirements, to for-profit POs. Consequently, the PACE regulations and requirements apply equally to all POs whether they are not-for-profit or for-profit. We have no reason to believe that the results of the evaluation would change if we added additional years to the study. We note that the majority of active POs are not-for-profit entities and most new applicants represent not-for-profit entities.

As a result of the comments, we are making no changes to our proposal and finalizing this provision as proposed.

In addition, we proposed to revise current paragraph (d)(3) (redesignated paragraph (c)(3)) regarding changes in the organizational structure of a PO and add a new paragraph (d) to address PO change of ownership (CHOW). Section 460.60(d)(3) currently provides that a PO planning a change in organizational structure must notify CMS and the SAA, in writing, at least 14 days before the change takes effect. We have stated in

[5] A copy of the 2008 Mathematica study results can be found here: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Downloads/Beauchamp_2008.pdf.*

[6] A copy of the 2013 Mathematica study results can be found here: *https://innovation.cms.gov/Files/reports/pace-access-qualityreport.pdf.*

guidance that a change in organizational structure is one that may affect the philosophy, mission, and operations of the PO and affect care delivery to participants, and would include any CHOW (see PACE Manual, Ch. 2, § 20.3).

In the 1999 IFC (64 FR 66241), we required POs to notify both CMS and the SAA at least 60 days prior to any change in their organizational structure and obtain advance approval for any change that involved a CHOW. In the 2006 final rule (71 FR 71264), we discussed the comments we received on this provision and explained it was not our intent to require POs to notify CMS and the SAA in writing every time there was a change in personnel or a change in the line of reporting of direct participant care staff. Based on comments that the 60-day timeframe was unnecessary, we elected to change the requirement to the 14-day requirement that is currently in place. We also deleted the requirement that changes in organizational structure must be approved in advance by CMS and the SAA, agreeing with commenters that POs have the ability to make such business decisions based on their individual circumstances. As CMS and the SAA are responsible for the health care provided to participants, we retained the 14-day notification requirement in § 460.60(d)(3) to allow CMS and the SAA sufficient time to monitor whether the change is having a substantial impact on the participants or their care. However, we reiterated that in the event of a CHOW, we would apply the general provisions described in the Medicare Advantage regulations at § 422.550.

Based on our experiences with PO CHOW since we published the 2006 final rule, we stated in the proposed rule that we no longer believed 14 days gives us enough time to review and process a CHOW. A CHOW is significantly different from other organizational changes in that it results in the acquiring entity assuming the responsibilities under the PACE program agreement. We explained we need additional time to determine whether the acquiring entity meets statutory and regulatory requirements for entering into a PACE program agreement. We noted that our ultimate responsibility is to the PACE participants, and we need to ensure that an entity is able to assume and fulfill the responsibilities of a PO under the PACE program agreement.

Moreover, we noted that the process to effectuate a CHOW transaction in our systems requires more time than the 14-day timeframe in the current regulation. For example, a minimum of 6 weeks is needed to effectuate changes in our payment systems for the new owner. A 60-day advance notification requirement is more consistent with that timing. We also stated that we wanted our regulations to be clear that the requirements in 42 CFR part 422, subpart L (Effect of Change of Ownership or Leasing of Facilities During Term of Contract), which apply to MAOs under the Medicare Advantage program, apply to POs in a CHOW scenario. Therefore, we proposed to amend newly redesignated paragraph (c)(3) to indicate that the 14-day timeframe does not apply to a CHOW, and to add new paragraph (d), which would specify that a PO planning a CHOW must comply with all requirements in 42 CFR part 422, subpart L, and must notify CMS and the SAA, in writing, at least 60 days before the anticipated effective date of the change. We stated that we believed this proposed change would provide the time we need to determine if the entity acquiring the PO meets all PACE requirements and would be able to continue providing quality care to the participants of the PO, and to reflect the change in our systems. We also noted that we believed the amended language as proposed would provide greater clarity to POs as to the requirements that will apply in CHOW scenarios. We stated that we believed the Medicare Advantage requirements for a CHOW in 42 CFR part 422 subpart L, are appropriate for the PACE program, and we will only enter into a PACE program agreement with an entity that is determined to meet PACE program requirements.

For purposes of the proposed provision, any CHOW as defined in § 422.550(a), such as an asset transfer, a merger, or change in partnership, would require a novation agreement, where the contract is substituted for the former contract. We explained that POs will need to follow all CHOW requirements in 42 CFR part 422, subpart L, and must submit all of the necessary documents to CMS for review within the allotted timeframes. Upon CMS' determination that the conditions for CMS approval of a novation agreement are met, a new PACE program agreement will be executed with the acquiring entity.

A discussion of the comments we received on the CHOW proposal, and our responses to those comments, appears below.

Comment: A few commenters stated the definition of a CHOW may encompass situations where the PO's parent entity or supporting entity undergoes a restructuring which has no impact on the PO itself. They also questioned if the 60-day notice and related requirements would apply in a restructuring of the PO's parent entity. The commenter suggested that, in these types of situations, the PO should not have to submit advance notice and comply with the requirements of 42 CFR part 422, subpart L.

Response: POs may contact us if they have questions on the applicable requirements and whether a particular scenario is a CHOW or a different type of change in organizational structure. If a PO is planning a CHOW as described in § 460.60(d) then the PO must follow the regulations at § 460.60(d) and provide the required notification.

Comment: A commenter requested that CMS clarify if the novation agreement is similar to the PACE program agreement.

Response: The novation agreement and PACE program agreement are two separate and distinct documents. The novation agreement is an agreement between the current owner of the PO, the prospective new owner, and us under which we recognize the new owner as the successor in interest to the current owner's PACE program agreement. The PACE program agreement will be the successor's PACE program agreement with CMS and the SAA for the operation of a PACE program by the successor PO.

Comment: Many commenters supported the proposal to expand the notification timeframe for a CHOW from 14 days to 60 days. One commenter requested that we consider the SAA's needs for advance notification for CHOW scenarios and add additional time to our requirement for notification.

Response: We work closely with the SAA as the third party to the PACE program agreement. We expect that as POs are seeking to undergo CHOW transactions that they communicate with the SAA prior to or at the same time as they communicate with us. We will consider the recommendation to allow for additional time to notify the SAA as part of future rulemaking or guidance.

Comment: A commenter requested that we limit the requirement for an entity to complete a PACE application for purposes of a CHOW as discussed in the HPMS PACE CHOW memo, Guidance on Notification Requirements for PACE Organization Change of Ownership, dated February 18, 2016, to apply only to those entities that have no experience with PACE program operations. Another commenter suggested that the successor in interest to the PACE CHOW should not have to go through the PACE application

process, but did not suggest an alternative for the qualification process.

Response: We want to reiterate our policy that in order for an acquiring entity to become qualified as a PO, the entity must follow both the CMS and the specific state's PACE application submission process. The application process provides a level of assurance to us, as well as the SAA, that the successor in interest to the PO has the ability to assume the obligation to provide care to the vulnerable population in PACE.

Comment: One commenter expressed concern that if a PO is seeking a CHOW due to a financial hardship or experiencing other difficulties, requiring the acquiring entity to become qualified through the PACE application process may make it impossible to prevent actions such as a PACE termination.

Response: We appreciate the comment and will continue to work with POs that are in these types of hardship situations to help ensure that their participants continue to receive proper care. Even though we have designated timeframes to complete the application approval process, when we are made aware of these types of extenuating circumstances, we work closely with the PO and the SAA to process the application as quickly as possible and prevent negative impact to the participants.

We appreciate the commenters' recommendations and will consider them as we develop subregulatory guidance on PO CHOWs. We will continue to require all entities that are not currently approved POs, but would like to be the successor in interest to a PO, to become qualified as a PO through our PACE application process. The PACE application process is an administrative process with established requirements that all entities have to meet in order to qualify as a PO. This application process demonstrates to us and the SAA that the successor in interest to the PO is qualified to be a PO and will maintain arrangements to comply with the legal and regulatory requirements for PACE and other requirements imposed under the PACE program agreement. This allows us to maintain a consistent qualification process for all entities. We are finalizing the CHOW requirements as proposed.

2. Governing Body (§ 460.62)

Section 460.62 focuses on the ability of the PO's governing body to provide effective administration in an outcome-oriented environment. As we have previously explained in the 1999 IFC (64 FR 66241) and the 2006 final rule (71 FR 71264), the governing body guides operations and promotes and protects participant health and safety, and it is legally and fiscally responsible for the administration of the PO. Additionally, the governing body must create and foster an environment that provides quality care that is consistent with participant needs and the program mission. To that end, we proposed to revise the language in § 460.62(a)(7) and to add new paragraph (a)(8). Currently, § 460.62(a)(7) references a ''quality assessment and performance improvement'' program. In addition to replacing that term with ''quality improvement,'' as discussed in section II.A. of this final rule, we also proposed to add a reference to the quality improvement program requirements in § 460.130, to make it clear that the governing body is ultimately responsible for ensuring the PO meets those requirements.

As we did not receive any comments on these proposed changes, we are finalizing this provision as proposed.

In addition, as discussed later in this section, we proposed in a new § 460.63 to require that all POs adopt and implement effective compliance oversight. Because the governing body is both legally and fiscally responsible for administration of the PO, and is responsible for ensuring that the organization provides quality care (see § 460.62(a)), we stated that we believed adoption and implementation of compliance oversight requirements is the responsibility of the governing body. We noted that having legal responsibility over the governance of the organization requires ensuring that the organization complies with federal and state regulations, adheres to contract requirements, and minimizes waste and abuse. To that end, we proposed to add a new § 460.62(a)(8) that specifies the governing body of the PO must have full legal authority and responsibility for adopting and implementing effective compliance oversight as described in § 460.63.

As discussed in detail in the following section, we received several comments on our compliance oversight proposal and as a result of those comments, we have decided not to finalize certain aspects of that proposal at this time, in order to allow CMS additional time to evaluate the potential burden that implementing certain aspects of the compliance oversight provision might have on POs. Relatedly, based on these comments and to allow additional time to evaluate the potential burden, we are not finalizing the proposal to add a new § 460.62(a)(8) specifying that the governing body of the PO must have full legal authority and responsibility for adopting and implementing the compliance oversight program.

3. Compliance Oversight Requirements (§ 460.63)

In the proposed rule, we discussed the compliance programs required under the Medicare Advantage (MA) and Medicare Part D programs, and noted that those programs have long been recognized as key to protecting against fraud, waste, and abuse. The importance of these programs has been highlighted by several of our oversight bodies. As is authorized by sections 1934(f)(3) and 1894(f)(3) of the Act, we proposed to adopt compliance oversight requirements in the PACE regulations. Specifically, at new § 460.63, entitled ''Compliance Oversight Requirements,'' we proposed to require each PO to have a compliance oversight program that is responsible for monitoring and auditing their organization for compliance with our regulations. Additionally, we proposed to require POs to have measures that prevent, detect and correct non-compliance with CMS' program requirements, as well as measures that prevent, detect, and correct fraud, waste, and abuse.

In determining what compliance oversight CMS should require of all POs, we considered as potential models the compliance program requirements for Medicare Part C organizations at § 422.503(b)(4)(vi) and the compliance program requirements for Part D sponsors at § 423.504(b)(4)(vi). POs offering qualified prescription drug coverage under Part D are already required to have a compliance program as a part of their Part D benefit, however, specific requirements of the Part D compliance program were waived for all POs. The Part D application took into account PACE as a direct care provider, as well as a payer, and it weighed the importance of maintaining compliance with CMS regulations with the need for flexibility as a direct care provider. All Part D compliance program elements were waived except the two elements that we proposed.

In § 460.63, we proposed to establish that the two elements of a Part D compliance program required of POs participating in Part D will become compliance oversight requirements for the PO as a whole. Specifically, we proposed to require each PO to adopt and implement effective compliance oversight, which includes measures that prevent, detect and correct non-compliance with CMS' program requirements, as well as measures that prevent, detect and correct fraud, waste and abuse that would include, at a

minimum: (1) The establishment and implementation of an effective system for routine monitoring and identification of compliance risks, which should include internal monitoring and audits and, as appropriate, external audits, to evaluate the PO, including contractors, compliance with CMS requirements and the overall effectiveness of the compliance oversight program; and (2) the establishment and implementation of procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensuring ongoing compliance with our requirements. As part of the system for promptly responding to compliance issues, we also proposed the requirements that a PO: (1) Conduct a timely, reasonable inquiry if it discovers evidence of misconduct related to payment or delivery of items or services, (2) conduct appropriate corrective actions in response to the potential violation (for example, repayment of overpayments or disciplinary actions against responsible employees), and (3) have procedures to voluntarily self-report potential fraud or misconduct to CMS and the SAA. We noted that the PO should already have these elements implemented for their Part D benefit to comply with the Part D regulations, but they would need to expand these efforts to cover all of the services provided by the PO.

As we explained in the proposed rule, POs are not currently required to conduct internal organization wide monitoring or auditing efforts. Through our experiences with MA and Part D organizations, we stated that we believed conducting monitoring and auditing is key to identifying and correcting issues of non-compliance with CMS requirements. We noted that we believed that by adding these two compliance oversight provisions we are balancing the duty of a PO to ensure compliance with CMS requirements with the need for flexibility as a provider of service. We stated that POs will also benefit from improving their ability to identify and correct compliance risks within their own organization.

Additionally, we proposed to require the PO to implement appropriate corrective action in response to any identified issues of non-compliance that POs may discover. We noted that, if finalized, we intended to verify compliance with this new requirement through monitoring or auditing of the PO.

We received public comments from POs, states and advocacy groups which were supportive of the effort to ensure appropriate protections are in place, but cautioned CMS about the potential burden associated with implementing these provisions. We analyzed our proposal and believe that the majority of the burden on POs associated with the proposed compliance oversight requirements is due to the first proposed element, the requirement that a PO develop and implement a system for monitoring and auditing their PACE operations. While we consider it a best practice for a PO to adopt a compliance program that includes conducting internal monitoring and auditing, we are not finalizing our proposal to require the PO to adopt a system for routine monitoring and auditing of the PO and its contractors at this time in order to further evaluate the potential burden of this proposal on smaller organizations. As Part D plan sponsors, POs must still conduct monitoring and auditing of their Part D benefit as required under 42 CFR 423.504(b)(4)(vi)(F). The second proposed element of the compliance oversight requirements, which requires promptly responding to non-compliance and voluntary reporting of identified issues, does not pose a significant burden on a PO. Therefore, we are finalizing the second element of this provision which would require POs to correct identified non-compliance and voluntarily report fraud and/or potential misconduct to CMS and the SAA. In large part, POs may utilize their already established Part D system to comply with these new requirements for responding to, correcting and reporting non-compliance and potential fraud, and because we are not increasing the scope of a PO's monitoring responsibilities, we anticipate only a minimal burden on the organization by implementing this modified provision.

The following is a summary of the public comments we received on the proposed compliance oversight requirements in new § 460.63 and our responses to comments. As a result of these comments, we are finalizing this provision in part.

Comment: A majority of commenters were supportive of our proposal to require POs to adopt a compliance oversight program. Commenters noted that adding compliance oversight requirements is an important step to ensuring POs are able to stop non-compliance and take appropriate corrective action. These commenters noted that this proposal would help ensure the safety of participants, and protect against fraud, waste and abuse.

Response: We appreciate commenters' support and agree that implementing a compliance oversight program is a best practice for all organizations, big or small, in order to ensure compliance with federal and state regulations. We hope that POs will consider increasing the scope of their monitoring and auditing efforts as part of their effort to ensure they are compliant with our requirements. We are not, however, finalizing the first element of our proposal which would have required POs to expand the scope of their monitoring efforts. Instead, we are only finalizing the second element, which requires POs to respond, investigate and correct non-compliance as it is identified. While we further evaluate the implications of a required compliance oversight program on the unique PACE model of care, we will continue to assess potential risk to participant safety through auditing and account management oversight, and address any identified fraud, waste and abuse issues as needed.

Comment: Multiple commenters raised concerns over the potential burden that implementing this provision would cause POs. Commenters stated that there are significant differences between MA/Part D organizations and POs; including the fact that MA/Part D organizations tend to have larger staffs and greater resources, as well as different program structures, which would make implementing this proposal more challenging for POs. Other commenters suggested that the burden on smaller organizations and rural organizations would be especially significant. Most commenters also requested that, if CMS finalizes this provision, that the implementation date be no earlier than 12 months following the regulation becoming final in order to allow organizations the appropriate time to determine how to appropriately implement a compliance oversight program and allocate resources. Several commenters suggested that CMS had underestimated the cost of implementing a compliance oversight program in PACE. One commenter requested that CMS work closely with stakeholders to determine technical assistance needs and practical implementation schedules before enacting this proposal.

Response: We appreciate commenters' concerns regarding the potential burden this provision may cause for POs. We have a significant policy interest in further assessing how to integrate an effective compliance oversight program,

as well as the potential burden and benefits related to expanding this provision across the PACE program. In order to minimize the potential burden associated with this provision, we re-analyzed the burden estimates and believe that the majority of costs are associated with the first element of our proposal, the element that would require POs to expand their auditing and monitoring efforts to cover their entire operation. While we consider it a best practice to conduct internal auditing and monitoring to identify non-compliance with PACE requirements, we are not finalizing that element of this provision at this time while we further evaluate the implications of this proposal on the unique PACE model of care. We are, however, finalizing the second element which would largely allow organizations to use their already established system to respond to and correct any non-compliance discovered in the POs. We anticipate only a minimal burden in finalizing this element and believe such efforts can be implemented in the 60 days following publication of the final rule.

Comment: Several commenters posed questions regarding the structure or administration of a compliance oversight program in PACE. Two commenters questioned if POs would be required to submit their compliance oversight program to CMS for approval. The same two commenters questioned if CMS would require the POs to implement specific structures, policies or procedures for the compliance oversight program. Another commenter questioned if CMS would offer technical assistance to POs.

Response: We appreciate the opportunity to provide clarification on this proposal. We understand that POs are both payers, as well as direct care providers. We also understand that POs vary greatly in size, structure and resources. As such, we believe that a PO should continue to be free to develop a compliance oversight program that works best for their specific organization. POs are already required to have systems in place to correct identified non-compliance and voluntarily report fraud or potential misconduct to us for their Part D benefit, and we do not anticipate that substantial changes would need to be made to the structure of such systems based on this provision as finalized. Additionally, while we would be willing to provide technical guidance to POs, we do not expect to collect documentation regarding the structure of a PO's compliance oversight program or provide an approval process. Instead, POs will have flexibility in designing their own compliance oversight programs so long as they ensure they are satisfying the requirements in the new § 460.63.

Comment: A few commenters questioned how CMS would monitor these compliance oversight programs in PACE. One commenter suggested CMS conduct rigorous monitoring of the compliance oversight programs. Another commenter questioned if CMS would validate the monitoring that POs did under their compliance oversight programs. One commenter requested that CMS ensure that any monitoring of the compliance oversight program is done consistently across regions.

Response: We may begin monitoring compliance with the requirements in § 460.63 as finalized during audits or other communications with POs. We agree that CMS monitoring should be done consistently and we intend to develop specific guidance for auditors or other personnel in CMS.

Comment: Several commenters expressed their support for our proposal to reduce the frequency of CMS audits and characterized it as being in exchange for requiring POs to develop their own compliance oversight requirements.

Response: We thank the commenters for their support. While we proposed both to decrease the frequency of our audits and to increase POs' self-monitoring, these policies were each intended to stand on its own and were not intended to be an exchange. While we are not finalizing the element of the proposed compliance oversight requirements that would have required POs to monitor and audit all operations, we believe that this is a best practice and would encourage organizations to expand the scope of their current monitoring and auditing efforts. We are finalizing the second element within this provision in order to ensure POs are promptly responding to, investigating and correcting potential compliance problems as they are identified. Separately, we are also finalizing our proposal to reduce the frequency of reviews by us in cooperation with the SAA under § 460.192, as discussed in the final rule below in Subpart K—Federal/State Monitoring.

Comment: One commenter recommended that the compliance oversight requirements for POs include all seven elements of the MA and Part D compliance programs, rather than just the two we proposed.

Response: We thank this commenter for the suggestion. While we believe that compliance programs are beneficial to all organizations, regardless of size, we decided at this time not to require POs to implement the seven compliance program elements required under MA and Part D. Under the Part D regulations, POs are required to have two of the seven elements of a compliance program implemented for their Part D benefit, but the other five elements are waived for POs. While we will continue to engage POs in discussions regarding the benefits of robust compliance programs, at this time we do not believe it is appropriate to require POs to implement the seven elements of the MA/Part D compliance program.

Comment: Several commenters suggested modifications to our compliance oversight proposal. A few commenters expressed concern with the potential burden of a compliance oversight program in PACE, and recommended we consider modifying the PACE compliance oversight program to account for the small size of some POs. These commenters recommended we refer to the OIG guidance on compliance programs for individual and small physician practices (see 65 FR 59434 through 59452).

Response: We appreciate these concerns and consistent with the OIG guidance cited by commenters, we took the size and structure of POs into account when proposing compliance requirements for PACE. As we mentioned in the proposed rule (81 FR 54677), we balanced the need for POs to maintain compliance with program requirements with the fact that they need flexibility as direct care providers. We initially proposed that of the seven compliance program elements in the MA and Part D programs, only two of these elements should be regulatory requirements for all POs. However, after reviewing the comments received, and because we have a significant policy interest in preventing undue burden, we are only finalizing one of the two proposed required elements. We believe there is a need for organizations to be able to identify non-compliance and fraud, waste and abuse, and to take corrective action when an issue is discovered. We also believe that since all POs already have a system in place to respond to identified compliance issues related to the Part D benefit, that finalizing this element will only create a minimal burden on POs.

Comment: Two commenters requested clarification on whether the PO must operate the compliance oversight program, or whether a parent organization of the PO could comply with the compliance oversight requirements on behalf of the PO.

Response: The regulation as finalized imposes compliance oversight

requirements on the PO, but we intended for these requirements to provide flexibilities for POs. Each PO must have procedures and an effective system for promptly responding to compliance issues and correcting problems, but we will not dictate what that system should look like or how it should be structured. Since POs are already required to have a system for responding to compliance concerns in their roles as Part D sponsors, we expect that many organizations will adapt their existing system to meet the PACE program requirements. However, the individual organization has discretion to choose to develop its compliance oversight program, including whether or not the compliance oversight program is run through the PO or another entity (such as a parent organization).

As discussed previously, a majority of commenters were supportive of our proposal to implement a compliance oversight program in PACE, while some commenters raised concerns regarding implementation and the associated burden of a compliance oversight program on small, direct care organizations. We agree with these commenters that further evaluation should be done to determine the potential burden associated with implementing this provision as proposed, but we believe that finalizing the second element within this provision would not impose a significant burden on organizations as, in large part, they may be able to use the systems for respond, investigate and correct compliance issues they have in place to comply with the requirements for Part D plan sponsors. Based on these comments, we are finalizing our proposed provision in part to require POs to adopt a compliance oversight program that requires POs to promptly respond to, investigate and correct potential non-compliance and fraud, waste and abuse.

4. Personnel Qualifications for Staff With Direct Participant Contact (§ 460.64)

Section 460.64 sets forth the personnel qualifications for staff with direct participant contact. In the 2006 final rule (71 FR 71267), we added a requirement at § 460.64(a)(3) that all personnel that have direct participant contact must have a minimum of 1 year of experience with a frail or elderly population. Our rationale was that the PACE population is comprised of frail or elderly individuals who must be cared for by staff with the specific training and experience necessary to understand the complexities and differences in geriatric patients.

However, as we explained in the proposed rule, we are concerned that many POs, especially those in rural settings, may have candidates for PO staff positions who meet all other qualifications for a specific position under § 460.64(a) but do not have 1 year of experience working with the frail or elderly population. We have approved several waivers of this requirement. For example, this situation often arises for positions such as van driver or transportation coordinator. We have received anecdotal reports that some POs encounter van drivers who have many years of relevant experience as school bus drivers but are unable to hire these drivers based on the requirement that staff with direct participant contact have 1 year of experience working with the frail or elderly population. We also have approved this type of waiver request for registered nurses (RNs), social workers, and other direct care providers.

As we stated in the proposed rule, we believe POs should be able to hire individuals who meet all other qualification requirements under § 460.64(a) except for the 1 year of experience requirement under paragraph (a)(3), and provide training to these individuals upon hiring. We explained in the proposed rule that this required training may be provided either through a training entity or directly by the PO. This training must be based on industry standards in order to provide these individuals with the skills necessary to work with the frail or elderly population in PACE. For example, through training, an individual would be taught about the complexities and differences in geriatric patients, and that he or she needs to be gentler, more patient and more observant than with a healthy, younger population. Therefore, we proposed to amend § 460.64(a)(3) to state that a member of the PO's staff (employee or contractor) who has direct participant contact must have 1 year of experience working with a frail or elderly population or, if the individual has less than 1 year of experience but meets all other requirements under paragraph (a) of § 460.64, must receive appropriate training from the PO on working with a frail or elderly population upon hiring. As we noted in the proposed rule, this would afford POs the flexibility to hire an otherwise qualified individual with less than 1 year of experience working with the frail or elderly population and subsequently provide the requisite training.

Current language in § 460.64(a)(4) requires staff with direct participant contact to meet a standardized set of competencies for a specific position established by the PO and approved by CMS before working independently. As we explained in the proposed rule, we continue to believe POs must establish a competency evaluation program for direct participant care staff as required by § 460.71(a)(2) and discussed in the 2006 final rule (71 FR 71267) to ensure that staff have the skills, knowledge and abilities needed to deliver safe care to participants. However, we stated in the proposed rule that we do not believe it is necessary for CMS to approve those competency evaluation programs prior to their use. We expect the PO to use current industry standards. Therefore, we proposed to revise to this paragraph to remove the reference to CMS approval. We also proposed to make technical, non-substantive changes to the language in paragraph (a) by changing the order of the current language in order to make the provision clearer and more concise.

A discussion of the comments we received on the proposed revisions to § 460.64, and our responses to those comments, appears below.

Comment: Commenters supported allowing POs to hire individuals with less than 1 year experience with the frail or elderly. Some commenters requested that CMS define ''appropriate training.'' One commenter requested that we require the training to be completed prior to the individual performing any direct care activities.

Response: We appreciate the commenters' support and will consider the request to define ''appropriate training'' and when it must be completed in the development of future guidance.

After considering the comments, we are making no changes to our proposal and are finalizing this provision as proposed.

5. Training (§ 460.66)

Section 460.66 requires the PO to provide training for staff members and to develop a specific training program for personal care attendants (PCAs). Paragraph (b) requires the PO to develop a training program for each PCA to establish the individual's competency in furnishing personal care services and specialized skills associated with the specific care needs of individual participants. Paragraph (c) states that PCAs must exhibit competency before performing personal care services independently. We proposed to redesignate § 460.66(b) and (c) to § 460.71, ''Oversight of Direct Participant Care,'' as new paragraphs (c) and (d), respectively, because § 460.71 already includes requirements regarding

training of staff and competency evaluations for employees and contracted staff furnishing care directly to participants. As we explained in the proposed rule, we believe including all of the related requirements in the same section would reduce confusion over applicable requirements. We did not propose any changes to the language in § 460.66(a) but proposed to remove the paragraph designation of paragraph (a).

We did not receive any comments on these proposed changes, and therefore, are finalizing this provision as proposed.

6. Program Integrity (§ 460.68)

Section 460.68 was established to guard against potential conflicts of interest and certain other risks individuals and organizations could present to the integrity of the PACE program. Section 460.68(a) addresses risks presented by a PO employing or contracting with persons with criminal convictions. Section 460.68(a)(1) addresses individuals and organizations that have been excluded from participation in the Medicare or Medicaid programs. Section 460.68(a)(2) addresses individuals and organizations who have been convicted of criminal offenses related to their involvement in Medicaid, Medicare, other health insurance or health care programs, or social service programs under title XX of the Act. Section 460.68(a)(3) currently states that a PO must not employ individuals or contract with organizations or individuals in any capacity where an individual's contact with participants would pose a potential risk because the individual has been convicted of physical, sexual, drug, or alcohol abuse.

As we explained in the proposed rule, we believed the current language in § 460.68(a) may not be tailored to effectively mitigate the risks that employing or contracting with certain individuals and organizations with prior convictions may pose to the PACE program, while still allowing POs to hire and contract with individuals who have had issues in their past that do not pose a risk to the PACE program. Accordingly, we proposed to amend § 460.68(a) by adding clarifying language to current paragraph (a)(3) and by adding two new paragraphs (a)(4) and (a)(5).

We noted in the proposed rule that the current language in § 460.68(a)(3) may have, in some cases, been overbroad so as to impair the PO's ability to hire or contract with appropriate staff. For example, under the current regulation, a PO is precluded from employing an individual with a conviction related to underage drinking, who has not had a conviction in adulthood, who is an otherwise appropriately qualified individual to work in a PO, and who would pose no foreseeable threat to participants. In such cases, persons who have previously misused alcohol and drugs and/or been diagnosed with alcohol use disorder or substance use disorder should not be categorically excluded from serving PACE participants.

In other instances, however, it is possible that an individual's past criminal conviction or convictions related to physical, sexual, drug, or alcohol abuse could provide POs with reason to believe that the individual may pose a threat of harm to participants. For example, there is a foreseeable risk of harm to participants if a PO employs a transportation driver who has a history of multiple Driving Under the Influence (DUI) convictions. We explained that we believed that it is important for POs to consider an individual's past criminal convictions and the potential risk to participants; however, we do not want to limit POs' ability to hire or contract with qualified individuals. This reflects the direction we have taken for long term care facilities (for example, § 483.12(a)(3)(i)), where specific restrictions are focused on individuals that are found guilty of abusing, neglecting or mistreating nursing home residents.

As such, we proposed to amend the language at § 460.68(a)(3) to enable POs to make a determination as to whether an individual's contact with participants would pose a potential risk because the individual has been convicted of one or more criminal offenses related to physical, sexual, drug, or alcohol abuse or use. We noted that POs are still bound by state laws governing the hiring of individuals that provide care and services to the frail elderly in state programs. We also noted that the current language in § 460.68(a)(3), which refers to ''drug, or alcohol abuse'' does not parallel the terminology used in criminal statutes, which often do not use the term ''abuse'' to describe the misconduct at issue, and also does not take into account criminal convictions that could be related to drug or alcohol use, such as DUIs, or drunken and disorderly conduct. Therefore, we proposed to amend the language to include ''drug, or alcohol abuse or use.''

We stated that although we do not want to foreclose POs from employing or contracting with qualified individuals or organizations that would pose no harm to participants despite past convictions, we proposed to add language in paragraphs (a)(4) and (a)(5), to impose additional limitations on POs employing or contracting with individuals or organizations that may pose a risk to participants. In new paragraph (a)(4), we proposed to add a restriction stating that a PO must not employ individuals or contract with organizations or individuals who have been found guilty of abusing, neglecting, or mistreating individuals by a court of law or who have had a finding entered into the state nurse aide registry concerning abuse, neglect, mistreatment of residents, or misappropriation of their property. This language parallels regulatory restrictions applicable to long term care facilities in § 483.12(a)(3)(i). We noted in the proposed rule that we believed these safeguards intended to protect residents in long term care facilities are equally appropriate protections for participants in the PACE program. In paragraph (a)(5), we proposed to add a restriction stating that a PO must not employ individuals or contract with organizations or individuals who have been convicted of any of the crimes listed in section 1128(a) of the Act. These offenses, which are bases for mandatory exclusion from federal health care programs, are: (1) Conviction of program-related crimes; (2) conviction relating to patient abuse; (3) felony conviction relating to health care fraud; or (4) felony conviction relating to controlled substance. Because we were proposing to add two additional paragraphs to paragraph (a), we proposed to remove the word ''or'' at the end of paragraph (a)(2). We also invited public comment on whether we should extend this provision to restrict hiring those with certain criminal justice histories to also include those with current restraining orders against them.

A discussion of the comments we received on this topic, and our responses to those comments, appears below.

Comment: Commenters expressed support for our proposal to allow POs discretion in hiring individuals who have prior convictions but do not pose a current risk to PACE participants. One commenter agreed with our proposal, with the caveat that there must be a high level of training provided to these individuals. One commenter requested we clarify if a PO could consider a conviction from another state.

Response: We welcome the commenters' support. We will consider the comments specific to training and convictions from other states in the development of future guidance and are finalizing the provisions as proposed.

Comment: In response to our request for comment related to excluding individuals with current restraining orders against them, commenters expressed concern that this would impose a higher standard than what is required for nursing homes.

Response: We thank the commenters for responding to our request for comments on a potential restriction for individuals with current restraining orders against them. Many commenters pointed out that this would result in inconsistency with regulatory requirements for long term care facilities. After considering the comments, we are not making any changes to the PACE rules at this time related to individuals with current restraining orders against them.

7. Contracted Services (§ 460.70)

Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act state that, under a PACE program agreement, a PO must furnish items and services to PACE participants directly or under contract with other entities. Accordingly, we require in § 460.70 that all administrative or care-related services, except for emergency services as described in § 460.100, that are not furnished directly by a PO must be obtained through contracts that meet the requirements specified in regulations. In the proposed rule, we solicited comments on whether contracted services authorized by the PO or services operated directly by the PO should comply with the Home and Community-Based Settings (HCBS) regulation at § 441.301(c)(4) when non-institutional settings are used to house and/or provide services to PACE participants, provided they do not conflict with requirements under this section. We noted that the HCBS settings requirements apply broadly to many different Medicaid authorities (including state plan services and waivers, such as sections 1915(c), 1915(i), and 1915(k) of the Act), but currently do not apply to the delivery of services by a PO under sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act. Because POs already support the majority of participants in non-institutional settings, we sought comments on whether or not CMS should apply the requirements to POs. Although we did not propose any changes requiring compliance with § 441.301(c)(4) when non-institutional settings are used to house and/or provide services to PACE participants, we solicited comments on possible proposals to do so in future rulemaking. Changes we considered and on which we solicited comments included:

- Adding a new paragraph § 460.70(b)(1)(iv) stating, a contractor must comply with the HCBS regulation at § 441.301(c)(4) when non-institutional settings are used to house, provide services to, or house and provide services to PACE participants, provided they do not conflict with requirements under this section.
- Adding a new paragraph § 460.98(b)(4) stating, the PO must comply with the HCBS regulation at § 441.301(c)(4) when non-institutional settings are used to house, provide services to, or house and provide services to PACE participants, provided they do not conflict with requirements under this section.

A discussion of the comments we received on this topic, and our responses to those comments, appears below.

Comment: Most commenters on the topic expressed that the PACE model of care is consistent with the principles and objectives of the HCBS rule, in that care is person-centered and affords individuals choice in where, how and from whom care is given. They stated that under current PACE regulations, POs are already required to ensure an individual's right to privacy, dignity and respect, and freedom from coercion and restraint. A commenter noted that participation in PACE is voluntary, and PACE provides a setting that creates a safe community of individuals to gather for meals and social stimulation to prevent isolation. Commenters expressed concern that a strict application of the HCBS requirement at § 441.301(c)(4) could prevent POs from providing care in the PACE center, where a large proportion of PACE participants access services, when it is often necessary for participants with dementia to attend the PACE center or alternative care setting to ensure their safety. In addition, commenters expressed concern that strict application of the HCBS regulation at § 441.301(c)(4) may impact POs' ability to provide care to PACE participants in ways that have been demonstrated to be successful at delaying or preventing nursing home placement. Commenters noted that it is just as important to allow individuals the right to choose to participate in activities at the PACE center or other congregate locations as it is to protect their right to participate in activities in other community settings. Commenters also expressed concern that application of the HCBS regulation at § 441.301(c)(4) would impact PACE service delivery. Some commenters suggested that application of the HCBS regulation at § 441.301(c)(4) has been inconsistent, and has caused confusion for some providers, and raises safety and access concerns for those caring for people with certain conditions, such as dementia.

Response: Based on our review of these comments, we agree with the commenters that many of the existing PACE objectives and requirements are consistent with the requirements of the HCBS regulation at § 441.301(c)(4). We also recognize that some of the principles of the HCBS settings requirements could be adopted in PACE to increase community integration requirements for POs as they facilitate participants' ability to reside independently in the community. Because POs have unique requirements to provide care in both institutional and non-institutional settings, and the role of the PACE center is so fundamental to the provision of PACE services, we believe it is important to be thoughtful before adding or expanding HCBS setting requirements to PACE. We appreciate all of the comments received on this issue, and we plan to use the feedback for consideration in future rulemaking.

Comment: While six commenters expressed support for applying the HCBS settings requirements to PACE, they also expressed some concerns that certain elements should or should not apply to PACE. For example, some commenters supported application of the HCBS regulation at § 441.301(c)(4) to all PACE settings except for the PACE center. One commenter suggested a delay in implementation of the HCBS regulation in PACE, or that CMS allow for flexibilities in applying HCBS settings requirements to PACE. Another commenter recommended that alignment of the HCBS regulation at § 441.301(c)(4) to PACE be postponed to a later rulemaking in recognition of the already integrated delivery structure and person-centered approach in PACE. Another commenter that supported the application of the HCBS settings requirements for non-intuitional settings in PACE stated that PACE participants living in settings such as assisted living and residential care facilities should be able to move into these types of setting. One commenter expressed concern that the eviction protection in the HCBS settings rules may conflict with the PACE involuntary disenrollment regulations. Some commenters supported application of the HCBS regulation at § 441.301(c)(4) to PACE, but stated that implementation should not have the unintended consequence of preventing POs or their contractors from providing housing or services that enable people to live independently in their homes and communities

(including supports for family caregivers).

Response: We appreciate the detailed comments about how the HCBS regulation at § 441.301(c)(4) should or should not apply in PACE, and will continue to evaluate the appropriateness of the application of the HCBS regulation in PACE and use this feedback for consideration in future rulemaking.

Comment: Some commenters stated that the HCBS settings requirements should be expanded to cover existing PACE programs, and that any HCBS provider must be held to the same standards and requirements. They expressed that even though PACE services often are provided at a specific PACE center, the availability of services at the center should not have the effect of isolating participants from the broader community. Some commenters expressed there is no reason why the HCBS settings requirements should not apply to PACE, since PACE, like other HCBS options and waivers, is designed to provide a non-institutional alternative for persons with LTSS needs. Therefore, they stated that any HCBS provided by POs, either directly or through contractual arrangements, should be subject to the HCBS regulation at § 441.301(c)(4). Several of the commenters recommended that CMS, in addition to incorporating the HCBS settings requirements in § 441.301(c)(4), should incorporate paragraph (c)(5). Paragraph (c)(4) sets standards for HCBS settings, and paragraph (c)(5) describes settings that cannot be considered home and community-based. Those commenters stated that POs and their contractors should comply with both of these paragraphs.

Response: While we believe that many of the existing PACE objectives and requirements are consistent with the requirements of the HCBS Settings final rule at 42 CFR part 441, we recognize that some of the principles of that rule could be adapted in PACE to increase community integration requirements for POs as they facilitate participants' ability to reside independently in the community. Because PACE differs from every other HCBS program in that POs are required to provide care in institutional and non-institutional settings and the PACE center is so fundamental to the provision of services, we believe it is important that we carefully and thoughtfully weigh many factors before adding or expanding HCBS setting requirements to PACE. As a result, we are not incorporating any HCBS settings requirements into PACE at this time. We appreciate all of the comments received on this issue, and plan to use the feedback for consideration in future rulemaking.

In addition to soliciting comments on the HCBS settings requirements, we proposed several revisions concerning contracts with entities that furnish administrative or care-related services. Section 460.70(d)(5) specifies the required terms for contracts with entities that furnish administrative or care-related services. Sections 460.70(d)(5)(vi) through (ix) address additional contract requirements where the PO chooses to contract with individuals as IDT members or key administrative staff. We explained in the proposed rule that, although the current provisions do not explicitly reference those individuals, this was our intent when we adopted the requirements in the 2002 IFC (67 FR 61498, 61505), and when we addressed these requirements in the 2006 final rule (71 FR 71270, 71335). We noted that this is also how we have interpreted the regulation in practice, however, we understand it has caused confusion for POs. To make the regulation clearer and reduce confusion, we proposed to add a new paragraph (d)(6) under which we proposed to redesignate § 460.70(d)(5)(vi) through (ix) as § 460.70(d)(6)(i) through (iv) and state that these contract requirements apply to individuals providing contracted services to the IDT or performing the duties of the program director or medical director. We also proposed to make a technical change to the language in former § 460.70(d)(5)(vii) (proposed § 460.70(d)(6)(ii)) to change ''meeting'' to ''meetings.''

We proposed to make a technical change to § 460.70(e)(2) to change ''PACE Center'' to ''PACE center'' consistent with the definition in § 460.6, and other references throughout the regulation. We proposed to revise § 460.70(e)(2) to correct the reference contained in that section by changing § 460.98(d) to be § 460.98(c).

A discussion of the comments we received on the proposed changes to § 460.70, and our responses to those comments, appear below.

Comment: Some commenters requested that we expand § 460.70, the existing regulation that requires POs to provide services directly or under contract with other entities, to allow the use of non-contracted providers.

Response: Under the scope of benefits described in sections 1894(b)(1) and 1934(b)(1) of the Act, a PO may enter into written contracts with outside entities to furnish services to participants that are not provided directly by the PO. Consequently, we require in § 460.70 that all services, except for emergency services as described in § 460.100, not furnished directly by a PO must be obtained through contracts which meet the requirements specified in regulations.

Comment: One commenter requested that we provide an exception to the contract requirements in § 460.70 for administrative or care-related services that are provided by a PO's parent organization.

Response: We would not grant such an exception as we expect the PO to have contractual arrangements for accountability purposes with all entities that furnish services not directly furnished by the PO (except emergency services), including the PO's parent organization. As the PO's parent organization can change, for example, when a CHOW occurs, it is essential that a contract is in place to show any existing relationship and services provided by the parent organization.

Because the statute requires POs to provide PACE services directly or through contracts with other entities, we do not believe we can expand § 460.70 to allow the use of non-contracted providers in PACE as requested by the commenters. After considering the comments, we are finalizing the changes to § 460.70 as proposed.

8. Oversight of Direct Participant Care (§ 460.71)

Section 460.71 identifies PO oversight requirements for employees and contracted staff with direct patient care responsibilities. Paragraph (a) requires the PO to ensure that all employees and contracted staff furnishing care directly to participants demonstrate the skills necessary for performance of their position, and further requires, under paragraph (a)(1), that the PO provide an orientation to all employees and contracted staff. Paragraph (b) requires the PO to develop a program to ensure that all staff furnishing direct participant care services meet certain requirements, including, under paragraph (b)(4) that they are free of communicable diseases and are up to date with immunizations before performing direct patient care.

We proposed to make some technical, non-substantive changes to paragraph (a)(1) that would make the provision more concise. We also proposed to amend paragraph (b)(4). As we explained in the proposed rule, our intent when we amended § 460.71 in the 2006 final rule was to reflect our current policy described in § 460.64(a)(5), which states that PACE staff (employees or contractors) who have direct

participant contact must be medically cleared for communicable diseases and have all immunizations up-to-date before engaging in direct participant contact (71 FR 71273). We noted that § 460.71(b)(4) was not amended in a consistent manner, which we understood caused confusion among POs about whether to attach the same meaning to ''medically cleared for communicable diseases'' and ''free of communicable diseases.'' Therefore, we proposed to amend § 460.71(b)(4) by referencing the language previously added to § 460.64(a)(5) so that both sections would be consistent and contain the same language.

As noted previously in our discussion of proposed changes to § 460.66, we proposed to move paragraphs (b) and (c) of § 460.66 related to personal care services furnished by PCAs to § 460.71(c) and (d), respectively.

A discussion of the comment we received on this topic, and our response to that comment, appears below.

Comment: One commenter stated that the proposed rule does not specify a minimum curriculum or minimum training standards for PCAs and suggested that the PACE manual define the minimal competencies that PCAs are expected to demonstrate before performing personal care tasks independently.

Response: As we have previously stated in our discussion on personnel qualifications for staff with direct participant contact (see subpart E.4. (Personnel Qualifications for Staff with Direct Participant Contact (§ 460.64)), it is our expectation that POs follow industry standards with respect to the skills required for working with the frail or elderly population in PACE. Therefore, we do not believe it is necessary at this time to specify minimum training standards or competencies for PCAs.

9. Physical Environment (§ 460.72)

Section 460.72 of the PACE regulations addresses requirements for the physical environment of the PACE center, including those pertaining to space and equipment, fire safety, and building safety. In the proposed rule, we noted that CMS had published in the December 27, 2013 **Federal Register** a separate proposed rule that would affect the PACE requirements for emergency preparedness that, at the time, were included in § 460.72 (see 78 FR 79802). This proposal has now been finalized. Specifically, on September 16, 2016, we published in the **Federal Register** a final rule titled ''Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers,'' which revised the PACE requirements at § 460.72 and added a new § 460.84. The final rule (81 FR 63860) established national emergency preparedness requirements for 17 types of Medicare- and Medicaid-participating providers and suppliers, including POs, to ensure that they adequately plan for both natural and man-made disasters, and coordinate with federal, state, tribal, regional, and local emergency preparedness systems. For a complete discussion of the PACE emergency preparedness revisions, see the September 16, 2016 final rule (81 FR 63904 through 63906).

10. Marketing (§ 460.82)

Section 460.82 addresses requirements governing the marketing activities of POs. Section 460.82 provides special language requirements, and paragraph (c)(1) states that a PO must furnish printed marketing materials to prospective and current participants in English and in any other principal languages of the community. We proposed to further clarify this requirement by defining what we mean by ''principal languages of the community.'' We noted in the proposed rule that, as we stated in the 2006 final rule (71 FR 71279), we believed the determination of a principal language of the community is a state determination. However, we recognized that not all states have an established standard for when a language is considered to be a principal language of the community (in other words, a language threshold). Where a state has not established such a standard, we proposed the following standard would be applied—a principal language of the community would be any language spoken in the home by at least 5 percent of the individuals in the PO's service area.

As we explained in the proposed rule, we referred to any language spoken ''in the home'' because U.S. Census data identifies the principal language as the primary language spoken in the home. We noted that we established a similar 5 percent language threshold for marketing materials in the Medicare Advantage program (§ 422.2264(e)), and we believed this threshold is also appropriate for PACE. Moreover, we stated in the proposed rule, we strive to create harmony across program requirements when feasible. This reduces complexity for those organizations that operate multiple CMS programs. We explained that, currently, in the MA program, we determine which MA organizations must provide translated marketing materials by using the U.S. Census Bureau's American Community Survey (ACS) data, and we then communicate that information to plans via HPMS. We noted that we did not propose to replace any state-based language thresholds; rather the goal was to provide a standard in instances where a state standard does not exist. Additionally, we noted in the proposed rule, we would not preclude POs from producing materials in alternative languages when those languages are spoken by less than 5 percent of the individuals in the PO's service area; rather we aimed to set a more clear standard for when furnishing such materials is a requirement.

We did not receive any comments on our proposal to use the same approach to the language threshold determination as we do in the MA program, and therefore, we are finalizing the provision as proposed.

Paragraph (e) pertains to prohibited marketing practices and places certain restrictions on PO employees and agents. Paragraph (e)(3) states that gifts or payments to induce enrollment are prohibited. As we stated in the proposed rule (81 FR 54680) and the 2006 final rule (71 FR 71279), this provision does not prevent a PO from offering gifts of a nominal value. For example, as we explained in the proposed rule and 2006 final rule, offering gifts to potential enrollees who attend a marketing presentation is permitted as long as these gifts are of a nominal amount and are provided whether or not the individual enrolls in the PACE program. The gift cannot be a cash gift or be readily converted into cash regardless of the amount. To ensure that our regulations reflect this distinction, we proposed to amend paragraph (e)(3) to specify that gifts or payments to induce enrollment are prohibited, unless the gifts are of nominal value as defined in CMS guidance, are offered to all potential enrollees without regard to whether they enroll in the PACE program, and are not in the form of cash or other monetary rebates. We stated in the proposed rule that CMS currently defines ''nominal value'' in section 30.10 of the PACE Marketing Guidelines (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pace111c03.pdf*) to mean an item worth $15 or less, based on the retail value of the item, which is consistent with the values in the marketing guidelines under the Medicare Advantage and Medicare Part D programs. We noted in the proposed rule that we believed the revision to paragraph (e)(3) would preserve our goal of ensuring that current and potential PACE participants and their families or

guardians elect PACE based on the merits of the program versus the enticement of a gift, while clarifying that POs have the ability to offer prospective participants a small gift such as a pen with the organization's name and contact information without the concern of violating the PACE marketing regulations. We stated that similar flexibility has been permitted under both the MA and Part D programs for several years with no notable adverse impact to participants. As such, we explained in the proposed rule, the PACE program will continue to look to these two programs to define the monetary value that constitutes a nominal gift. In addition, and consistent with the MA and Part D programs, we stated in the proposed rule that the PACE regulatory definition of a nominal gift would exclude any gifts in the form of cash or monetary rebates.

Section 460.82(e)(4) prohibits contracting outreach efforts to individuals or organizations whose sole responsibility involves direct contact with the elderly to solicit enrollment. Due to the particular nature of the PACE program and the PACE population, we stated in the proposed rule that we believed it is in the best interest of the program to only permit POs to market their programs through their own employees. Therefore, we proposed amendments to this section to specifically prohibit POs from using non-employed agents/brokers, including contracted entities, to market PACE programs.

As we explained in the proposed rule, the decision to enroll in a PACE program is significantly different from the decision to enroll into other Medicare or Medicaid managed care programs because PACE participants must agree to receive all medical care (as well as other services) from the PO into which they enroll. This may mean PACE participants must give up longstanding relationships with health care providers, as well as become liable for the costs of any unauthorized services. We noted that this is an important distinction that non-employed agents and brokers may overlook when they market PACE programs to potential participants. Agents and brokers that do not work for POs often sell other products, such as Medicare Advantage and Medicare PDP products. These products are significantly different from PACE in many respects, including the services that are covered, the ways in which participants receive the services, and the enrollment requirements for participants.

In the proposed rule, we expressed concern that these substantial differences, combined with the typical low enrollment numbers associated with the PACE program, make it difficult for agents and brokers that are not employed by POs to fully understand and explain the PACE program to potential participants. We emphasized that our concern was less about false marketing (which connotes a malicious action) and more about enrollment numbers not becoming the primary motivation when marketing PACE. An independent third party would likely not have the opportunity to develop the necessary expertise to act as agents employed by a PO. We stated we believed employees of the PO would be the best equipped to provide potential participants and their caregivers with accurate information about the PO, the services it provides and the ramifications of receiving services not approved by the PO's IDT. We noted this is especially important given the vulnerable nature of the PACE population, which is elderly and frail and often has more complex health care needs than Medicare or Medicaid managed care populations, for which the use of non-employed agents and brokers for marketing may be more appropriate.

As we discussed in the proposed rule, we believed that only permitting POs to use employees for marketing activities would help ensure potential PACE participants fully understand the program, the rules, how to access services, and the ramifications of not accessing services through the PO. Accordingly, we proposed to amend § 460.82(e) to remove the term ''agents'' and simplify the language. The revised provision would preclude POs from using certain prohibited marketing practices. In conjunction with that revision, we proposed to amend paragraph (e)(4) to prohibit marketing by any individuals other than the employees of the PO. We noted that some POs may have existing arrangements with independent agents and brokers and that, as with other functions, POs may delegate such responsibilities to an outside entity. We solicited comments as to whether CMS' proposed prohibition on the use of independent agents and brokers is appropriate. We stated that if commenters believed that this prohibition is not appropriate, they should provide specific reasons for allowing their use, descriptions of how POs contemplate using agents and brokers, and the protections POs have in place to ensure accurate information is provided to potential PACE participants. We describe the comments we received on this proposal and our responses at the end of this section.

Section 460.82(e)(5) prohibits unsolicited door-to-door marketing. We proposed to add language to § 460.82(e)(5) specifying that any other unsolicited means of direct contact, including calling or emailing a potential or current participant without the individual initiating contact, is a prohibited marketing practice under PACE. We explained that unsolicited contact, for example, through telephone (also known as ''cold calling'') or email, is similar to, and generally as prevalent if not more prevalent, than door-to-door marketing, which is already expressly prohibited under § 460.82(e)(5). We stated the purpose of this addition is to clarify that unsolicited means of direct contact through telephone and email are not allowed under PACE. Although we declined in the 2006 final rule to expand this prohibition beyond door-to-door solicitation, we stated we would continue to monitor marketing practices by POs and would propose additional safeguards as appropriate (71 FR 71279). We explained in the proposed rule that based on the vulnerability of the population served by the PACE program and the increase in health care fraud we have seen since 2006, we believed a prohibition on other unsolicited means of direct contact is appropriate for PACE. Moreover, we noted, such a prohibition is consistent with our marketing requirements for MA organizations (§ 422.2268(d)) and PDP sponsors (§ 423.2268(d)).

We also proposed to remove § 460.82(f), which requires that POs establish, implement, and maintain a documented marketing plan with measurable enrollment objectives and a system for tracking its effectiveness. We explained that based on the insight we have gained through years of oversight responsibility for the PACE program, we believed the requirement for a marketing plan is redundant. We noted in the proposed rule that we believed that the pertinent information captured in the plan is attainable through other account management activities. For example, POs convey marketing strategy in regularly scheduled meetings with their CMS Account Managers. We explained that the CMS Account Managers are also made aware of marketing materials and messages, as well as the intended audience for such materials and messages, through the marketing submission and review process. In addition, CMS has a separate method for tracking enrollment data.

A discussion of the public comments we received on our marketing proposals, and our responses to those comments, appears below.

Comment: Commenters expressed concerns that the proposed simplified language under § 460.82(e)(4) could be construed as also prohibiting states and advocates from educating potential participants about PACE. Several commenters expressed that POs should maintain the flexibility of using contracted entities to assist them with marketing activities. Two commenters expressed agreement with our proposal to restrict marketing to employees of the PO. One such commenter expressed concern with fraud, confusion, and abuse associated with marketing by non-employees, while the other commenter did not provide a reason for agreeing with the proposed restriction.

Response: As a result of the comments, we note that the proposal to restrict marketing to employees of the PO was not intended to preclude states and advocacy groups from discussing PACE with potential participants. To clarify this position, we are revising § 460.82(e)(4) to prohibit marketing by any individual or entity that is directly or indirectly compensated by the PO based on activities or outcomes, as opposed to marketing by any individuals other than employees of the PO. We are also revising our proposal to differentiate between those entities which receive some level of compensation from the PO based on activities or outcomes in marketing PACE on behalf of the PO, and those who are educating potential participants on a host of potential healthcare choices, but are not compensated by the PO based on any activity or outcome, such as State Health Insurance Assistance Programs (SHIPs) and other advocates in the community.

Additionally, based on the majority of comments received, we believe it is best to be less prescriptive with regard to who can and cannot engage in marketing activities under PACE and to instead revise our proposal to address the root concerns of non-PO staff marketing PACE, such as a lack of understanding of the nuances of the PACE program and/or PO that could lead to an enrollment decision that is contrary to the best interest of the potential participant. Specifically, we are revising § 460.82(e)(4) to allow marketing by an individual or entity that is directly or indirectly compensated by the PO based on activities or outcomes if the individual or entity has been appropriately trained in PACE program requirements, including but not limited to 42 CFR part 460, subparts G and I of this part, addressing participant rights and participant enrollment and disenrollment, respectively. We are also adding provisions in § 460.82(e)(4)(i) and (ii) that state POs are responsible for the activities of contracted individuals or entities who market on their behalf, and that POs that choose to use contracted individuals or entities for marketing purposes must develop a method to document training has been provided, respectively.

By outlining expectations for the appropriate training combined with reiterating that the PO is responsible for marketing activities conducted by others on its behalf, we believe we are providing additional flexibility to POs while still safeguarding potential and current PACE participants. Moreover, we believe that this change will address the concerns of fraud, confusion, and abuse expressed by the commenter who was in favor of the proposed agent marketing prohibition.

We are finalizing the other proposed changes to the marketing requirements—§§ 460.82(c)(1), 460.82(e) introductory text, 460.82(e)(3), and 460.82(e)(5)—as outlined in the proposed rule.

G. Subpart F—PACE Services

1. Service Delivery (§ 460.98)

Section 460.98 addresses service delivery under PACE. We proposed to make a technical change to the heading of § 460.98(d) to replace ''PACE Center'' with ''PACE center'' for consistency with other references in § 460.98 and throughout part 460. Likewise, in paragraph (d)(3) we proposed to replace ''Pace center'' with ''PACE center'' for the same reason.

We also solicited public comments on potential changes to our PACE center requirements, which originated from the PACE Protocol. As defined in § 460.6, a PACE center is a facility which includes a primary care clinic, areas for therapeutic recreation, restorative therapies, socialization, personal care, and dining, and which serves as the focal point for coordination and provision of most PACE services. Under § 460.98(b)(2), PACE services must be furnished in at least the PACE center, the home and inpatient facilities, and under § 460.98(c), certain minimum services must be furnished at each PACE center. Section 460.98(d) requires a PO to operate at least one PACE center either in, or contiguous to, its defined service area with sufficient capacity to allow routine attendance by participants. A PO must ensure accessible and adequate services to meet the needs of its participants and, if necessary, must increase the number of PACE centers, staff, or other PACE services. If a PO operates more than one center, each PACE center must offer the full range of services and have sufficient staff to meet the needs of participants.

As we explained in the proposed rule (81 FR 54681) and the 2006 final rule (71 FR 71283), we believe the success of the PACE delivery model has been predicated on the combination of the IDT assessment, care planning, and the PACE center. The PACE center requirement established in the original PACE Protocol provides a point of service where the primary care clinic is located, where services are provided, and socialization occurs with staff that is consistent and familiar. The IDT not only works from the PACE center, it also provides the majority of services to participants at the PACE center, where most participants come on a regular basis to receive the majority of their care. Attendance at the center has been considered an important aspect of the PACE model of care, which helps to differentiate it from home health care or institutional care. We noted that more recently, CMS has allowed participants to receive services at alternative care settings. However, those services are meant to supplement, not replace, the services that the PACE center must furnish.

We further explained in the proposed rule that, over the years, we have received a number of requests to provide greater flexibility with respect to the PACE center operation and service requirements. We have heard concerns that the development costs and the length of time required to establish a PACE center can be significant and inhibit expansion of existing programs. To better understand the issues facing POs, in the proposed rule, we solicited public comment on ways to revise the current regulatory requirements to allow greater flexibility with regard to the settings in which IDT members provide PACE services, while still ensuring that PACE participants can receive the full range of services and benefits that has made PACE such a successful model of care for this population. We stated that we will use public comments to inform future PACE rulemaking concerning how to allow greater flexibility with regard to the settings in which IDT members provide PACE services.

A discussion of the public comments we received on this topic, and our responses to those comments, appears below.

Comment: Commenters generally supported potentially allowing POs

greater flexibility to utilize alternative care settings (for example, adult day care centers, senior centers, or activity areas in residential communities). One commenter recommended that CMS modify PACE requirements consistent with certain principles including, for example, that PACE participants must be assigned to a PACE IDT, but the IDT does not have to be assigned to a PACE center. Many commenters stated that the ability to deliver care in alternative care settings would provide POs more flexibility in responding to participants' needs and preferences, and promote PACE growth and expansion in ways that are not constrained by POs' ability to construct new PACE centers. However, other commenters expressed concern regarding the potential for significant movement away from delivering care at the PACE center, which is considered the essence of the PACE model of care, toward increased reliance on providing care in settings outside the PACE center. One commenter suggested that increased flexibility in service delivery settings for PACE may result in the program becoming more like network-based Medicare and Medicaid managed care programs. Another commenter suggested that providing more flexibility to POs with respect to service delivery settings could result in an ''unlevel playing field'' between POs and other health plans serving similar populations. Therefore, this commenter recommended that as CMS works to introduce flexibilities around the PACE program, it should align standards and requirements for POs with those for other Medicare and Medicaid managed care plans where appropriate.

Commenters also suggested that CMS would need to consider and provide an opportunity for comment on the potential need for alignment across CMS programs of various operational and program requirements.

Response: We appreciate the thoughtful comments and recommendations provided by commenters. The feedback will help inform future PACE rulemaking.

Comment: Many commenters supported testing use of the PACE model of care for new populations under section 1115A of the Act, which was afforded by the PACE Innovation Act of 2015 (PIA), including testing the PACE model of care for individuals younger than 55 with disabilities, who are currently ineligible for PACE because of their age. Some commenters expressed concern regarding the opportunity to test expansion of PACE under this authority. For example, one commenter stated that any future model test under section 1115A of the Act, as amended by the PIA, to serve individuals with psychiatric disabilities should be governed by the January 16, 2014 Medicaid final rule [7] that establishes the requirements and limits applicable to Medicaid HCBS in order to restrict the use of a PACE center as a location for the delivery of services to this population. Another commenter urged us to use the authority provided by the PIA to find affordable ways to extend the PACE model of care to older adults with Medicare who need LTSS but are not eligible for Medicaid. Finally, the Medicare Payment Advisory Commission (MedPAC) urged us to consider changes to the PACE rate setting and risk adjustment methodologies to increase the accuracy of payments under any model test.

Response: We appreciate the recommendations on potential tests of the PACE model of care under the authority of section 1115A of the Act, as amended by the PIA. We will continue to consider future opportunities to conduct model tests under this authority. However, our focus currently is on developing models through which we would directly contract with a range of Medicare providers and suppliers, and these providers and suppliers would agree to be accountable for cost and quality in providing care to a defined beneficiary population. We are working to ensure these potential models would provide opportunities to test innovative ways to serve people of all ages who have complex chronic conditions and/or functional impairments, building on what has worked well with the PACE clinical approach. Comments on the PIA are beyond the scope of this rule, as this rule pertains to the existing PACE program, and any potential waivers of existing PACE regulations, changes to payment methodology or modifications to eligibility criteria for a model test under section 1115A of the Act as amended by the PIA would be addressed as appropriate for each model. However, we will take the commenters' input, as well as the comments received in response to the PACE Innovation Act Request for Information [8] issued December 23, 2016, into account as we develop future model tests.

Comment: In response to a proposed revision to the IDT role of the primary care provider, commenters suggested a corresponding revision to § 460.98(c)(1) to state that primary care services furnished at the PACE center may be provided by a physician, nurse practitioner or physician assistant.

Response: Section 460.98(c)(1) currently refers to primary care services as including physician and nursing services. However, as discussed in section III.G.3. of this final rule, we proposed and are finalizing changes to § 460.102(b) and (c) to permit primary medical care to be furnished by a primary care provider, meaning a primary care physician, a community-based physician, a physician assistant (provided certain requirements are met), or a nurse practitioner (provided certain requirements are met). We appreciate the suggested revision and agree that it would help ensure consistency between the two sections of the regulation. Therefore, we will revise § 460.98(c)(1) to refer to the minimum services furnished at each PACE center as including ''primary care, including services furnished by a primary care provider as defined in § 460.102(c) and nursing services.'' This change will recognize that primary care can be provided not only by physicians and nurses, but also by other types of primary care providers, as defined in § 460.102(c).

Comment: One commenter requested that we provide more detailed guidance with respect to alternative care settings in PACE.

Response: We did not propose any changes regarding alternative care settings, so we consider this topic to be beyond the scope of this rule. We direct the commenter to the guidance we issued on alternative care settings in PACE. (See the June 30, 2016 HPMS memorandum, Clarification on the Requirements for Alternative Care Settings in the PACE Program.)

2. Emergency Care (§ 460.100)

Section 460.100 addresses emergency care under PACE. We proposed to make a technical revision to § 460.100(e)(3)(i) by replacing references to ''POs'' and ''PO'' with references to ''PACE organizations'' and ''PACE organization,'' respectively, to make the language consistent throughout § 460.100 and with other references in part 460.

We did not receive any comments on this proposal, and therefore, we are finalizing the change as proposed.

[7] *https://www.federalregister.gov/documents/2014/01/16/2014-00487/medicaid-program-state-plan-home-and-community-based-services-5-year-period-for-waivers-provider.*

[8] See *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/PACE/PACE-Innovation-Act.html.*

3. Interdisciplinary Team (§ 460.102)

Section 460.102 sets forth the requirements for an IDT, which are based on provisions in Part IV, section B of the PACE Protocol (64 FR 66248). As we have stated previously in preambles to rules and subregulatory guidance (*http://cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pace111c08.pdf*), we believe a well-functioning IDT is critical to the success of the PACE program because the team is instrumental in controlling the delivery, quality, and continuity of care. Further, members of the IDT should be knowledgeable about the overall needs of the participants, not just the needs that relate to their individual disciplines (64 FR 66248; 71 FR 71285; 81 FR 54682). Section 460.102(a)(1) requires that the PO establish an IDT at each PACE center to comprehensively assess and meet the individual needs of each participant. Section 460.102(b) specifies the composition of the team and provides that it be comprised of at least the 11 members listed in the section.

Under sections 1894(f)(2)(B)(iii) and 1934(f)(2)(B)(iii) of the Act, the IDT approach to care management and service delivery is a requirement that cannot be waived. However, we explained in the proposed rule that we understood there may be circumstances when it would be difficult for a PO to have a separate individual fill each of the 11 IDT roles, which may be an obstacle for the expansion of the PACE program, especially in rural areas. To provide greater flexibility for POs, we proposed that a PO be permitted to have one individual fulfill two separate roles on an IDT when the individual meets applicable state licensure requirements and is qualified to fill each role and able to provide appropriate care to meet the participant's needs. For example, we noted, a registered nurse cannot fill the role of a Master's-level social worker unless the registered nurse also has a master's degree in social work. Under § 460.190 and § 460.192, CMS and the SAA monitor POs during the trial period and perform ongoing monitoring after the trial period to ensure that POs are in compliance with all PACE requirements. We explained in the proposed rule that these monitoring activities will serve as a safeguard to help ensure there is no negative impact to the quality of care being provided. During these reviews, CMS and the SAA can confirm that when an IDT member is serving in two IDT roles, participants' needs are still being met. As such, we proposed to revise paragraph (a)(1) to state that the IDT must be composed of members that fill the roles described in paragraph (b). We also proposed to revise paragraph (b) to state the IDT must be composed of members qualified to fill, at minimum, the following roles, in accordance with CMS guidelines. We stated that we will publish the IDT guidelines in HPMS following publication of the final rule. We noted that paragraph (b) would also state that one individual may fill two separate roles on the IDT where the individual meets applicable state licensure requirements and is qualified to fill the two roles and able to provide appropriate care to meet the needs of participants.

A discussion of the public comments we received on our proposal regarding IDT roles, and our response to those comments, appears below.

Comment: Commenters supported the proposal to allow one individual to fill two separate roles on the IDT where the individual has the appropriate licenses and qualifications for both roles.

Response: We appreciate the support for this proposal and will finalize the revisions as proposed. As noted previously, we will publish IDT guidelines in HPMS following the publication of the final rule.

Section 460.102(b)(1) currently provides that the IDT must include a primary care physician, and § 460.102(c) requires that primary medical care be furnished by a PACE primary care physician who is responsible for managing a participant's medical situations and overseeing a participant's use of medical specialists and inpatient care. As we stated in the proposed rule, we are aware that changes in the practice of medicine and state licensing laws have expanded the practice of non-physician practitioners (for example, nurse practitioners), such that these practitioners in many cases are able to fulfill the role served by the primary care physician. Thus, including those individuals on the IDT in the role of the primary care provider may prove to be more operationally feasible and cost-effective, particularly in rural areas or areas where labor costs may be high. We noted that we have approved requests by POs to waive the requirement at § 460.102(b)(1) and (c) so that primary medical care can be furnished by someone other than a primary care physician on the IDT, thus allowing POs to deliver care through a non-physician primary care provider (such as a nurse practitioner or physician assistant) or a community-based physician. We stated that we have typically granted such waivers, and we have not encountered any issues or concerns with the quality of care provided by non-physician primary care providers or community-based physicians acting in this capacity on behalf of and working collaboratively with the PACE primary care physician or medical director.

As we explained in the proposed rule (81 FR 54682), 1999 IFC (64 FR 66248), and the 2006 final rule (71 FR 71285), the role of primary care physician on the IDT was based on the PACE Protocol and codified in regulation. In the 2006 final rule, we explained that we considered expanding this role to include nurse practitioners but decided to retain the PACE Protocol requirement. We noted our view at the time that it would be acceptable to include a nurse practitioner on the IDT, but it should be in addition to rather than instead of a primary care physician. We also stated in the 2006 final rule that such a change should be included in a proposed rule in order to allow for public comment on this issue; and in the meantime we would continue to assess the appropriateness of allowing nurse practitioners to assume the role of the primary care physician consistent with state licensure requirements for nurse practitioners (71 FR 71285).

As discussed in the proposed rule, the PACE program agreement has replaced the PACE Protocol. We noted that, like certain other requirements that were based on the PACE Protocol, we believed the composition of the IDT needs to change to reflect evolving medical practices and technologies. We stated that we believed it is appropriate to expand the primary care physician role on the IDT to include certain other primary care providers. Accordingly, we proposed to revise § 460.102(b)(1) to specify that a primary care provider, rather than a primary care physician, must be part of the core IDT. Further, we proposed to revise § 460.102(c)(1) to permit primary medical care to be furnished by a primary care physician, a community-based physician, a physician assistant (provided certain requirements are met), or a nurse practitioner (provided certain requirements are met). We also proposed to revise § 460.102(c)(2) to refer to primary care provider rather than primary care physician. We stated that these changes would allow all POs to furnish primary care through these other types of providers, thereby reducing burden on the POs without compromising care.

For physician assistants and nurse practitioners, we proposed to add language in paragraphs (c)(1)(iii) and (iv) to require that they be licensed in accordance with state law and practice within their scope of practice as defined

by state laws with regard to oversight, practice authority, and prescriptive authority. We noted that, with increasing shortages of primary care providers across the country, we believed affording POs the flexibility to involve other non-physician practitioners practicing collaboratively with the PACE primary care physicians would enable the POs to accommodate more participants and expand their programs, without comprising quality of care.

We proposed redesignating the current language in paragraph (e) as paragraph (f) and, in a new paragraph (e), we proposed to add language that references the requirements in § 460.71, which sets forth guidelines for the oversight of employees and contracted staff that have direct patient contact. We explained that referencing § 460.71 should make it clear to POs that they must ensure that all members of the IDT demonstrate the skills necessary for the performance of their positions as required under § 460.71. Additionally, we noted, this will require the PO to confirm that all members of the IDT comply with state certification or licensure requirements for direct patient care in their respective settings. The PO and its medical director are responsible for the oversight of all care provided to PACE participants.

A discussion of the public comments we received on our proposal regarding primary care providers on the IDT, and our responses to those comments, appears below.

Comment: Commenters strongly supported revising the regulations to require a primary care provider to serve on the IDT instead of requiring a primary care physician. This would permit nurse practitioners, physician assistants, and community-based physicians to fill this role. Some commenters suggested what they believed to be necessary corresponding revisions to other sections of the PACE regulations related to the settings in which a primary care provider provides services. Specifically, commenters suggested that we clarify in § 460.98 whether a primary care provider may provide services in a community-based setting. Similarly, the commenters requested a clarifying revision to § 460.98(c)(1) regarding the primary care services furnished at the PACE center. A few commenters recommended that a nurse practitioner be listed as a provider who can serve as the medical director for a PO. Commenters also questioned if the PO's medical director must be a medical doctor.

Response: We appreciate the support for the proposed revisions to § 460.102 regarding the primary care provider and will finalize that change to the regulation as proposed. Regarding the suggestion that we clarify whether a primary care provider may provide services in a community-based setting, we do not believe that a clarification is necessary in light of the removal of the ''primarily served'' requirement discussed below. We do appreciate the suggested clarifying revision to § 460.98(c)(1) to ensure consistency between the two sections of the regulation. As discussed in section III.G.1. of this final rule, we are revising § 460.98(c)(1) to refer to ''primary care, including services furnished by a primary care provider as defined in § 460.102(c) and nursing services''. Regarding the role of the PACE medical director and which disciplines can serve in this capacity, we initially proposed regulation text at § 460.60(b) that would require a PO to employ or contract with a physician in accordance with § 460.70, to serve as its medical director responsible for the delivery of participant care, for clinical outcomes, and for the implementation, as well as oversight, of the quality improvement program. However, at this time, we are not finalizing the change to specify that a physician must as serve as the medical director. We intend to address questions regarding the PACE medical director role in future guidance or rulemaking.

Currently, § 460.102(d)(3) states that the members of the IDT must serve primarily PACE participants. The ''primarily served'' requirement was part of the original PACE Protocol (64 FR 66249). However, section 903 of BIPA authorizes the Secretary to modify or waive such provisions in a manner that responds promptly to the needs of PACE programs relating to areas of employment and the use of community-based primary care physicians. We proposed to revise § 460.102(c)(1) to allow community-based physicians to fill the role of primary care provider on the IDT. As we explained in the proposed rule, community-based physicians are different from the PACE primary care physician. The PACE primary care physician works for the PO and is responsible for all PACE participants within the PO. The community-based physician generally works in a different practice, outside of the PO, but may also contract with the PO in order to work with select PACE participants who prefer to continue to receive their primary care services from their community-based physician. Community-based physicians usually provide care for the patients in community settings, such as outpatient clinics, and patients in those community settings often become PACE participants. Newly enrolled PACE participants often request to continue receiving care from their community-based physician. We noted in the proposed rule that we wanted to allow this flexibility for PACE participants because we believed it supports the continuity of care for participants. Therefore, we proposed to amend § 460.102(d)(3) to allow flexibility with respect to community-based physicians by excluding them from the requirement that they serve primarily PACE participants. As proposed, community-based physicians would be able to continue working in their community settings while contracting with the POs to provide PACE services. We also stated in the proposed rule that, in combination with the revision to paragraph (b)(1), this would effectively be a global waiver of the IDT member and ''primarily served'' requirements for community-based primary care physicians.

A discussion of the public comments we received on our proposal regarding the ''primarily served'' requirement, and our responses to those comments, appears below.

Comment: Most commenters concurred with eliminating the ''primarily served'' requirement for community-based physicians and suggested that this be extended to other types of community-based providers and possibly all members of the IDT.

Response: We thank the commenters for their support for this change. In response to these comments, as well as in response to comments we received on the alternative IDT proposals that are discussed next, we are finalizing changes to the ''primarily served'' requirement that renders our proposal on community-based physicians unnecessary. Changes to the ''primarily served'' requirement are further discussed below.

In the proposed rule, we also considered two alternative possibilities for revising parts of § 460.102 to provide greater flexibility to POs without compromising quality of care. In the first alternative, we considered deleting the requirements in § 460.102(b) related to the composition of the IDT. As noted previously, under sections 1894(f)(2)(B)(iii) and 1934(f)(2)(B)(iii) of the Act, the IDT approach to care management and service delivery is a requirement that cannot be waived. However, the PACE statutes do not specifically address the composition of the IDT.

As we explained in the proposed rule, we continue to believe that a well-

functioning IDT is critical to the success of the PACE program, as the team is instrumental in controlling the delivery, quality, and continuity of care. As we stated in the proposed rule (81 FR 54683) and the 1999 IFC (64 FR 66248), members of the IDT should be knowledgeable about the overall needs of the patient, not just the needs which relate to their individual disciplines. In order to meet all of the health, psychosocial, and functional needs of the participant, team members must view the participant in a holistic manner and focus on a comprehensive care approach. We noted in the proposed rule that we considered whether to provide even greater flexibility to POs, while maintaining our expectation of a well-functioning, knowledgeable IDT, by deleting the IDT composition requirements in § 460.102(b). Under this alternative approach, we would expect the composition of the IDT could be tailored based on each individual participant and the PO would continue to assess the need for services and provide all necessary services. Similar to the revisions to § 460.102(c), we would require that primary care be furnished by a PACE primary care provider. CMS and the SAA would continue to monitor POs to ensure that participants are receiving all necessary care. We noted that these monitoring activities would serve as a safeguard to help ensure there is no negative impact to the quality of care being provided. We stated that we believed this alternative approach of deleting the IDT composition requirements in § 460.102(b) could provide greater flexibility to POs without compromising the quality of care. We solicited public comments on this approach. A discussion of the comments we received on this option, and our response to those comments, appears below.

Comment: Most commenters expressed opposition to deleting IDT composition requirements. Several suggested that we retain the composition requirement for an IDT but modify it to allow for a range of health professionals and functions that participate in assessment and care planning based on the needs of individual PACE participants. One commenter thought that we should continue to require every member of the IDT to be present in the development of a participant's plan of care.

Response: We thank the commenters for their input on the first proposed alternative approach. In response to a majority of commenters who expressed concern regarding the deletion of IDT composition requirements, we have determined that the current requirements should be retained at this time.

As discussed in the proposed rule, in the second alternative, we considered deleting § 460.102(d)(3), which requires that members of the IDT must serve primarily PACE participants. Again, this requirement was based on the PACE Protocol, which has now been replaced by the PACE program agreement. As we stated in the proposed rule (81 FR 54683), the 1999 IFC (64 FR 66249) and the 2006 final rule (71 FR 71286), for a frail elderly population, such as is served by the PACE program, it is important to support and retain measures that promote quality and continuity of care. We explained that if team members serve primarily PACE participants, they are able to develop a rapport with participants and are better able to plan for and provide their care. Over the years, we have received and approved numerous requests to waive the ''primarily served'' requirement for members of the IDT, such as the primary care physician or the Master's-level social worker, in order to allow POs needed flexibility in staffing their IDTs. We have not encountered any issues or concerns after granting such waivers. Thus, we solicited public comments on whether we should extend this flexibility to all POs without the need to request a waiver.

Comment: Most commenters concurred with eliminating the ''primarily served'' requirement for community-based physicians and suggested also eliminating the requirement for other types of community-based providers and all members of the IDT. In addition, some commenters believed that the current requirement, *i.e.* ''primarily serve'' is vague and has led to misinterpretations of this requirement. In addition, commenters emphasized the operational challenges POs face, which can lead to a need for qualified staff that can serve on a part-time, rather than full-time basis. Other commenters stated that the use of community-based physicians has expanded the range of primary care providers PACE participants can choose from, and in many cases has permitted participants to retain their existing primary care physician when enrolling in PACE. A few commenters recommended retaining the ''primarily served'' requirement and expressed concern that members of the IDT should be knowledgeable and experienced with the needs of the PACE population. One commenter acknowledged that including community-based physicians on the IDT likely promotes continuity of care for newly-enrolled participants, but may cause conflicts regarding treatment and the approval of services over time. This commenter asserted that the inclusion of community-based physicians should continue to be addressed through the waiver process. Other commenters supported the proposals but indicated that protections must be in place to ensure the integrity of the PACE organization's mission.

Response: We have carefully considered the comments we received on this proposal, as well as the comments we received on the similar proposal related to community-based physicians. Overall, commenters were very supportive of the change to eliminate the ''primarily served'' requirement for individuals who serve on the IDT. However, some commenters expressed concerns about eliminating this requirement based on the belief that providers that primarily serve PACE participants, with presumably more direct and extensive experience rendering care to the PACE population, would be best positioned to understand and address the needs of those participants. While we understand this concern, we believe that community-based providers, regardless of their experience serving a PACE population, nonetheless must have the requisite expertise and ability to practice within the scope of their licensure. As long as these community-based providers are willing to fulfill the requirements for members of the IDT, we do not believe they should be precluded from doing so based on a requirement that they ''primarily serve'' PACE participants. Comments received were supportive of our proposals overall and support our conclusion that the benefits of requiring IDT members to have experience serving PACE participants, in and of itself, do not outweigh the benefits of eliminating the ''primarily served'' requirement. We note, as did certain commenters, that a number of waivers have been granted of the ''primarily served'' requirement for members of the IDT in recent years, with beneficial results. Furthermore, we are not aware of any adverse impact in overall quality of care for POs operating under such waivers. We agree with commenters that use of community-based providers has promoted continuity of care, allowed POs greater flexibility in the delivery of primary care to participants, and has increased operating efficiencies without compromising quality of care. We note that quality of care provided by POs will continue to be a focus of CMS and SAA oversight and monitoring activities. By reducing operational challenges and expanding PACE participant provider

choices, we continue to support efforts to ensure PACE participants have access to quality care and qualified providers. Based on the supportive comments we received, as well as our positive experience in granting waivers of the ''primarily served'' requirement, we are revising the regulations to delete the requirement that members of the IDT must serve primarily PACE participants. Specifically, we will update the regulation by removing § 460.102(d)(3).

4. Participant Assessment (§ 460.104)

Section 460.104 sets forth the requirements for PACE participant assessments. As we explained in the proposed rule (81 FR 54683) and the 2006 final rule (71 FR 71288), the information obtained through the participant assessment is the basis for the plan of care developed by the IDT. As such, it is important that the assessment be as comprehensive as possible to capture all of the information necessary for the IDT to develop a plan of care that will adequately address all of the participant's functional, psychosocial, and health care needs.

Section 460.104(a) sets forth the requirements for the initial comprehensive assessment, which must be completed promptly following enrollment. Currently all members of the IDT must be present for the initial assessment, representing each required clinical discipline to appropriately assess the PACE participant's holistic needs and develop a customized plan of care. We stated in the proposed rule that, under our proposal to modify § 460.102, to the extent an IDT member serves multiple roles on the IDT, that member may represent the clinical expertise for which he or she is qualified. Other team members may be present as necessary. In § 460.104(a)(2), we state that certain members of the IDT must evaluate the participant in person as part of the initial comprehensive assessment but, in paragraph (a)(1), we do not specify that the initial comprehensive assessment must be an in-person assessment. Therefore, we proposed to add the phrase ''in-person'' after ''initial'' in paragraph (a)(1). We explained that our longstanding policy has been that the initial assessment is an in-person assessment, so the addition of this language should make this requirement clear but not change the current practice. We also proposed to change the requirement that the initial comprehensive assessment be completed ''promptly following enrollment'' to ''in a timely manner in order to meet the requirements in paragraph (b) of this section.'' We noted in the proposed rule that this would allow the PO to complete this assessment at a time that works for the PO, but within a timely manner so as to allow the IDT to complete the development of the plan of care within 30 days of the date of enrollment.

Currently, during the initial comprehensive assessment, a primary care physician must evaluate the participant and develop a discipline-specific assessment of the participant's health and social status. We proposed to change ''primary care physician'' to ''primary care provider'' in paragraphs (a)(2)(i) and (c)(1) to be consistent with proposed changes to the composition of the IDT in § 460.102. As discussed in section III.G.2. of this final rule, we proposed that the primary care physician role be changed to primary care provider to allow other licensed primary care providers (specifically, nurse practitioners, physician assistants, and community-based physicians) to be part of the core IDT.

In § 460.104(a)(2), we proposed to remove the reference to IDT members initially evaluating participants ''at appropriate intervals'' because the scheduling of the discipline-specific assessments as part of the initial comprehensive assessment is up to the POs, and we believed stating that they must occur ''at appropriate intervals'' is unnecessary and superfluous language. We proposed to change the language in § 460.104(a)(3) from ''individual team members'' to ''the interdisciplinary team'' so that language is consistent throughout these regulations and because it is the IDT's decision whether to include other professionals in the initial comprehensive assessment. Additionally, we proposed to add the word ''initial'' before ''comprehensive assessment'' so it is clear that professionals may be included in the initial comprehensive assessment, as opposed to a reassessment. We proposed two changes to § 460.104(a)(4) to clarify that the initial comprehensive assessment covers all aspects of the participant's physical, social, and mental needs. Currently, the heading is titled ''Comprehensive assessment criteria.'' We proposed to revise the heading to ''Initial comprehensive assessment criteria.'' We also proposed to add ''in-person'' to this section to make it consistent with the terminology in § 460.104(a)(1) and (2). We stated in the proposed rule that we believed an initial comprehensive assessment is a more valuable tool for identifying the participant's need for services when performed in person.

Section 460.104(b) states that the IDT must ''promptly'' consolidate discipline-specific assessments into a single plan of care for each participant through discussion ''in team meetings.'' We noted in the proposed rule that the term ''promptly'' does not provide definitive direction for an IDT to know when the discipline-specific assessment should be completed and incorporated into a plan of care. We proposed to change this provision to specify that the plan of care must be completed ''within 30 days of the date of enrollment'' to remove the ambiguity of ''promptly.'' We stated that we believed 30 days balances the need for time to complete these activities with the need to complete these activities within a reasonable amount of time.

Moreover, we noted in the proposed rule, it is our understanding that some POs interpret the term ''team meeting'' as requiring members of the IDT to be physically present in the meeting. We stated that we believed POs need the flexibility to determine the format and location of IDT discussions to best meet the needs of PACE participants while not burdening the IDT by requiring these discussions to be held in face-to-face meetings. In paragraph (b), we proposed to change the words ''discussion in team meetings'' to ''team discussions'' to indicate that there must be a team discussion, but the format (for example, video conferencing, conference call, or in-person meeting) and location of the discussion would be at the discretion of the PO.

We also proposed to create a new paragraph under § 460.104(b). Under new paragraph (b)(1), we proposed to state that if the IDT determines from its assessment that any services associated with the comprehensive assessment criteria listed in paragraph (a)(4) do not need to be included in a participant's plan of care, the IDT must document in the participant's plan of care the reasons such services are not needed and are not being included. We explained in the proposed rule that if the IDT does not believe a PACE participant needs a certain service as it relates to the IDT care plan assessment findings, and therefore, does not authorize that service, the IDT must document the rationale for not including the service in the plan of care. We noted that we would expect the plan of care to reflect that the participant was assessed for all services even where a determination is made that certain services were unnecessary at that time. We proposed to move the current requirement in paragraph (b)—that female participants must be informed that they are entitled to choose a qualified specialist for women's health services from the PO's network to furnish routine or preventive

women's health services—to new paragraph (b)(2).

Currently, § 460.104(c) sets forth the requirements for periodic reassessments, including semiannual and annual reassessments. Section 460.104(d) discusses the requirements for unscheduled reassessments. We noted in the proposed rule that our experience has demonstrated that the requirement to perform both semiannual and annual reassessments can be overly burdensome and unnecessary in that participants are consistently being monitored for changes and are already reassessed whenever there is a change in their health status. Accordingly, we proposed to delete the requirement in paragraph (c)(2) requiring the annual reassessments by the physical therapist, occupational therapist, dietician, and home care coordinator. We proposed to delete corresponding references to annual reassessments in paragraph (d). We proposed to keep the requirement that PACE participants be reassessed semiannually, every 6 months. We stated that we would change the list of IDT members that must conduct the semiannual assessment to include the primary care provider, registered nurse, Master's-level social worker, and any other IDT members actively involved in the development or implementation of the participant's plan of care, as determined by the IDT members whose attendance is required. We noted in the proposed rule that we believed PACE participants should be reassessed at least every 6 months as this will better ensure that PACE participants, who are generally frail, are receiving appropriate treatment. We proposed to remove ''recreational therapist or activity coordinator'' from the list of IDT members that must participate in the semiannual reassessment. As stated in the proposed rule, we believed reducing the number of IDT members who are required to participate in the semi-annual assessment will reduce the burden on POs and allow the POs to allocate their resources more efficiently, while still meeting the care needs of participants. We explained in the proposed rule that POs have reported that recreational therapists and activity coordinators are not needed at every reassessment. POs further report that to require that recreational therapists or activity coordinators be present at every semiannual reassessment is unnecessary and can be overly burdensome. However, recreational therapists and activity coordinators are part of the IDT and can update the IDT on the participants' successes or needs for recreational therapy or involvement in activities. We stated in the proposed rule that we believed the primary care provider, registered nurse, and Master's-level social worker can collectively determine, based on the participant's plan of care and IDT discussions, which other IDT members should be present during the semiannual assessment. As such, we stated that we did not believe we needed to require that the recreational therapist or activity coordinator be present at the semiannual reassessment unless the primary care provider, registered nurse, and Master's-level social worker determine that the recreational therapist or activity coordinator needs to be present because that individual is actively involved in the development or implementation of the participant's plan of care.

The requirements for semiannual reassessments are currently at (c)(1)(i) through (v) and would be redesignated as paragraphs (c)(1) through (c)(4). In the redesignated paragraph (c)(1), we proposed to revise ''physician'' to ''provider'' for consistency. We also proposed to redesignate paragraph (c)(1)(v) as (c)(4) and revise the provision to delete the examples.

Section 460.104(d) discusses unscheduled reassessments. We proposed changes to paragraph (d) to remove the reference to annual reassessments. We proposed to change the language in (d)(1) from ''listed in paragraph (a)(2) of this section'' to ''listed in paragraph (c) of this section.'' As we explained in the proposed rule, this would change the requirement for unscheduled reassessments in the case of a change in participant status so that only the IDT members listed in paragraph (c) will have to conduct the unscheduled reassessment. Specifically, the primary care provider, registered nurse, Master's-level social worker, and other team members actively involved in the development or implementation of the participant's plan of care would conduct the participant's unscheduled reassessment. Similarly, we proposed to change paragraph (d)(2), regarding unscheduled reassessments at the request of the participant or the participant's designated representative, to also align with IDT members listed in paragraph (c). We noted in the proposed rule that we believed reducing the number of IDT members that are required to conduct the unscheduled reassessments would reduce the burden on POs and allow the POs to allocate their resources more efficiently, while still meeting the care needs of participants.

We noted in the proposed rule that, under § 460.64, PO staff with direct participant contact must only act within the scope of their authority to practice. Therefore, if the IDT members believe a participant may need care that is not within the scope of their respective practices, those members would need to involve other IDT members as appropriate. We stated in the proposed rule that, for these reasons, we did not believe we needed to require all core members of the IDT to conduct unscheduled reassessments.

A discussion of the public comments we received on our proposals regarding participant assessments under § 460.104, and our responses to those comments, appears below.

Comment: Some commenters did not support the proposed changes to § 460.104(d)(1) and (2) as they believed that not all service requests require an in-person assessment by each of the IDT members included in paragraph (c). These commenters suggested the IDT should retain the ability to determine which members of the IDT should conduct the reassessment, and include those IDT members that are actively involved in the participant's plan of care. Another commenter stated that some PACE participants have become overwhelmed by the large number of IDT members managing their care and, as a result, have disenrolled from the PACE program. Several commenters expressed the need to make the most effective use of IDT resources while meeting the needs of PACE participants. Lastly, a commenter requested that CMS clarify whether it has any concerns that providing POs with this greater flexibility could impact the quality of care for PACE participants.

Response: In an effort to align § 460.104(d)(1) and (d)(2), we inadvertently increased the number of IDT members required for in-person reassessments in (d)(2). In support of our efforts to reduce provider burden and balance the needs of PACE participants and PO resources, we believe that POs should retain the ability to identify the appropriate IDT members needed for an unscheduled reassessment at the request of the participant or designated representative as § 460.104(d)(2) currently permits, and we did not intend to require all IDT members referenced in § 460.104(c) to participate in conducting these reassessments. We do not anticipate that maintaining the current requirement will impact the quality of care for PACE participants as we will continue to rely on POs to apply their clinical expertise when conducting unscheduled reassessments and expect that the IDT will involve other IDT members as appropriate.

Based on the comments received about unnecessary and potentially overwhelming IDT member presence at reassessments, as well as the implications of our inadvertent change to align requirements, we are not finalizing the IDT member changes to § 460.104(d)(2) as proposed and will maintain the current requirement.

Comment: In general, commenters concurred with the proposed revisions to § 460.104. However, commenters expressed concern regarding the proposed revision to § 460.104(c)(2) that would eliminate the requirement for annual reassessments that include the other team disciplines such as physical therapist (PT), occupational therapist (OT), dietician, and home health coordinator. Commenters stated that by deleting the annual reassessment by the other team disciplines, POs may miss an opportunity to identify new or emergent participant issues. Commenters believed that an annual assessment by these disciplines is beneficial for the PACE participant.

Response: We appreciate the comments regarding the role of the other team disciplines, such as PTs, OTs, dieticians and home health coordinators, in patient assessments and that they continue to be included in an annual assessment. However, we will continue to require reassessments to be performed on a semiannual basis, that is, every 6 months. We believe that the primary care provider, registered nurse, and Master's-level social worker who participate in the semiannual reassessment can collectively determine, based on the participant's plan of care and IDT discussions, which other IDT members should be present during this reassessment. We expect the other disciplines, such as OTs and PTs, to be included as needed. As previously stated, PO staff with direct participant contact must only act within the scope of their authority to practice, so if the IDT members listed in paragraph (c) believe a participant may need care that is not within the scope of their respective practices, those members should involve other IDT members as appropriate. For these reasons, after considering the comments, we are finalizing the changes to § 460.104(c)(2) as proposed.

Comment: Commenters suggested that we allow POs to conduct in-person initial comprehensive assessments and reassessments using modern technology such as video conferencing, where participants and the IDT members are able to interact ''face-to-face'' and in real time but from different locations. Another commenter requested CMS allow for the use of remote technologies, noting that doing so would be particularly helpful in rural areas due to longer travel times and higher costs associated with conducting in-person reassessments. Other commenters expressed that not all service requests warrant an in-person reassessment. These commenters noted that in some cases, such requests could easily be addressed by the IDT members most familiar with the participant and actively involved in the plan of care. These IDT members would evaluate the request and update the care plan accordingly.

Response: We appreciate the recommendations regarding the use of modern technology in conducting initial assessments and reassessments and minimizing the burden associated with in-person reassessments for service requests, especially those requests that do not involve complex clinical decision making and/or input from specialty providers. In addition, we recognize that the current in-person requirements for unscheduled reassessments in response to service requests can sometimes delay access to services because of the time necessary to coordinate among the appropriate IDT members and conduct the in-person reassessment. Based on the comments we received in response to the discussion of PACE participant assessments in the proposed rule, we have carefully examined the reassessment requirements to determine whether it may be appropriate for a reassessment to be conducted via remote technology in some circumstances, as suggested by commenters, to ensure timely delivery of services and reduce burden on POs. As a result of feedback from the industry recommending that we allow the use of remote technology to reduce the burden associated with in-person reassessments, and to more efficiently address the care needs of PACE participants and afford POs more flexibility, we are revising § 460.104(d)(2) to specify that POs may use remote technologies to perform unscheduled reassessments in some circumstances. Specifically, when a participant (or his or her designated representative) makes a request to initiate, eliminate or continue a particular service, also known as a service request, the appropriate members of the IDT, as determined by the IDT, may use remote technologies to conduct unscheduled reassessments when the IDT determines that the use of remote technology is appropriate, the service request will likely be deemed necessary to improve or maintain the participant's overall health status, and the participant or his or her designated representative agrees to the use of remote technology. While we are not eliminating the requirement to perform unscheduled reassessments in response to service requests, or to conduct those reassessments in person in certain cases, we believe that permitting POs to use remote technologies to conduct reassessments under the circumstances described above will facilitate appropriate evaluation of PACE participants and promote the timely delivery of care and effective communication between the IDT and the participant and his or her designated representative. The regulation will continue to require POs to conduct a reassessment in response to a service request. However, we are revising the regulation to allow the appropriate member(s) of the IDT, as identified by the IDT, to conduct the reassessment using remote technology in specific circumstances. We expect that POs will use remote technology for service requests that are necessary to maintain participants' health and well-being in the community setting, and may include services such as improving sanitary conditions in the home, respite care, or items needed to manage and treat non-complex medical conditions. Additionally, POs must still conduct an in-person reassessment prior to denying a service delivery request and cannot use remote technology to conduct these reassessments.

We want to emphasize that remote technologies should be used on a case-by-case basis and may not be appropriate for participants that have complex medical needs and/or require a more hands-on approach for conducting unscheduled reassessments. We expect IDT members to utilize their clinical judgment in determining when remote technologies are appropriate and when an unscheduled reassessment should be conducted in-person, without using remote technologies.

In addition, we expect that circumstances may arise that warrant a follow-up ''in-person'' reassessment. For example, during an unscheduled reassessment initially conducted using remote video technology, the IDT may determine that a more extensive evaluation is needed that cannot be accomplished through remote technologies. We consider remote technologies that allow interactive and immediate dialogue between the IDT and the PACE participant, caregiver, and/or designated representative to be appropriate for conducting reassessments. This includes reassessments via telephone, video

conferencing, live instant messaging and chat software, or other media that allow sufficiently direct and interactive communication to permit the IDT to assess the participant's health status and evaluate the need for a particular service.

Based on our audit findings and general oversight of POs, we have found that the majority of service requests are approved, and can and should be processed by POs in a more expeditious manner. Audits conducted during calendar years 2017 and 2018 found that many service requests were not processed in a timely manner, leading to delays in the provision of the requested service. According to the 2017 PACE Annual Report, 55 out of 74 POs were cited for not processing service requests in a timely manner. Feedback from the POs suggests that the administrative burden associated with conducting in-person reassessments often causes delays in processing service requests and decision making regarding whether to approve or deny a request. Because the majority of service requests are approved, we have determined that the use of remote technologies is most appropriate for this type of unscheduled reassessment because it will reduce travel times and help to more expeditiously connect the IDT to PACE participants in the community, especially those who reside in rural settings and/or receive the majority of care in settings outside the PACE center due to physical or cognitive limitations or participant preference. We also believe this policy will help to prevent delays in care for fairly straightforward service requests that do not involve complex clinical decision making.

We emphasize that the use of remote technologies will be voluntary for participants, and POs cannot mandate that participants and/or their caregivers or designated representatives utilize such technologies during unscheduled reassessments. If a participant does not wish to allow for reassessments to be conducted with remote technologies, the IDT must conduct the reassessment in-person without using remote technology.

We encourage POs to utilize remote technologies as appropriate to improve communication with participants in all aspects of care delivery, however, use of remote technology does not supersede requirements that mandate in-person reassessments. This includes unscheduled reassessments at the request of the participant or designated representative where the PO would deny a request; under § 460.104(d)(2), we will continue to require POs to conduct an in-person reassessment before denying a request from a PACE participant.

The timeframe for notifying the participant or designated representative of the PO's decision to approve or deny the request will remain unchanged, and must be done in accordance with § 460.104(d)(2)(ii) through (iv). We also note that under § 460.104(e)(4), POs must furnish any approved services in the revised plan of care as expeditiously as the participant's health condition requires.

Lastly, at this time we do not believe it would be appropriate to conduct initial comprehensive assessments and other periodic reassessments through remote technologies. These assessments must continue to be performed in-person without the use of remote technology because they help to establish and/or maintain the therapeutic relationship between PACE participants and/or their caregivers and the PO, and we do not want to create circumstances in which the IDT misses an opportunity to identify new or emergent participant issues due to the inherent limitations of remote technologies, especially in circumstances where a more hands-on approach and/or in-person visualization is needed to more accurately and effectively evaluate participant care needs. In summary, with the exception of IDT member requirements in § 460.104(d)(2), we are finalizing all the other changes to § 460.104 as proposed. In addition, based on public comments, we are further amending the regulation in § 460.104(d)(2) to allow for the use of remote technologies to conduct unscheduled reassessments in response to service delivery requests when the IDT determines that the use of remote technology is appropriate and the service request will likely be deemed necessary to improve or maintain the participant's overall health status and the participant or his or her designated representative agrees to the use of remote technology.

5. Plan of Care (§ 460.106)

Section 460.106 requires that the IDT establish, implement, coordinate, and monitor a comprehensive plan of care for each participant. As we noted in the proposed rule, the purpose of the plan of care is to help support the identification of potential or actual areas of improvement and monitor progression and outcomes. The current regulatory language pertaining to the basic requirement and the content of the plan of care in this section has been described by POs as confusing and unclear. Therefore, we proposed to revise this section by adding requirements to provide more clarity without changing the fundamental aspects of the plan of care process.

First, we proposed to change § 460.106(a) from requiring that a plan of care be developed promptly to state that the plan of care must be developed ''within 30 days of the date of enrollment.'' We explained in the proposed rule that the term ''promptly'' does not provide definitive direction for an IDT to know when the discipline-specific assessments under § 460.104(b) should be completed and incorporated into a plan of care. Requiring that the plan of care be developed within 30 days of the date of enrollment balances the need for time to complete the assessments and develop a plan of care with the need to complete the plan of care within a reasonable timeframe. We noted that this proposed change is consistent with the proposed changes to § 460.104(b).

Next, we proposed to add language to clarify which members of the IDT are required to develop the plan of care within 30 days. The proposed language stated that the IDT members specified in § 460.104(a)(2) must develop the plan of care for each participant based on the initial comprehensive assessment findings. We noted in the proposed rule that the added language aimed to clarify for POs which members of the IDT should develop the plan of care. The IDT members in § 460.104(a)(2) are members of the IDT that are required to conduct the initial comprehensive assessment and would remain responsible for developing the plan of care based on the initial discipline-specific assessments. We acknowledge here that both §§ 460.104(b) and 460.106(a) mention the development of a plan of care, however, only § 460.106(a) includes changes that reference the IDT members in § 460.104(a)(2). We clarify here that the intent of § 460.104(b) is to achieve consensus among all IDT team members in developing one single plan of care, and that requirement is unchanged in this rule. The changes to § 460.106(a) specify which IDT members must be involved in the development of the plan of care based on their expertise and insights gained from conducting those comprehensive initial assessments, while § 460.104(b) maintains the requirement that the single plan of care must have the consensus of all IDT members through team discussions with the full IDT as indicated in the regulation and preamble discussions. In other words, while the eight disciplines responsible for conducting initial assessments will actively develop the proposed plan of care, the care plan

cannot be finalized without a team discussion with the full IDT included in § 460.102(b)(1) through (11) to gather input from all remaining IDT members and consensus from the full team. We believe that all members of the IDT bring valuable perspectives to this process and therefore reiterate that the changes to the IDT members required to develop the plan of care in § 460.106(a) do not impact the requirement in § 460.104(b) that all IDT members agree upon the plan of care through team discussions.

Section 460.106(b) sets forth the content of the plan of care and states that the plan of care must meet the following requirements:

- Specify the care needed to meet the participant's medical, physical, emotional and social needs, as identified in the initial comprehensive assessment;
- Identify measurable outcomes to be achieved.

We noted in the proposed rule that we believed these requirements are appropriate, but may have, in the past, led to confusion regarding the overall purpose, goal, creation, implementation and follow-up process of the plan of care. We stated that current regulations do not explicitly require POs to follow industry standards in developing and following care plan interventions. We noted that we believed adding new requirements will help POs to effectively and efficiently identify and address each participant's care planning needs. Therefore, we proposed to add three new requirements to § 460.106(b). In paragraph (b)(3), we proposed to require that the plan of care utilize the most appropriate interventions (for example, care improvement strategies) for each of the participant's care needs that advances the participant toward a measurable goal and desired outcome. In paragraph (b)(4), we proposed to require that the plan of care identify each intervention and how it will be implemented. We stated in the proposed rule that interventions should be targeted, specific actions implemented to improve a participant's health care outcome. And finally, in paragraph (b)(5), we proposed to require that the plan of care identify how each intervention will be evaluated to determine progress in reaching specified goals and desired outcomes.

The following is a summary of the public comments we received on the proposed changes to the plan of care requirements in § 460.106 and our responses to comments.

Comment: Overall, commenters supported the proposed revisions to § 460.106. A few commenters urged CMS to provide exceptions for extenuating circumstances (such as when a participant is hospitalized or out of the service area during the initial 30 days of enrollment, or services are disrupted due to catastrophic weather-related events) to the requirement for developing a comprehensive plan of care within 30 days of the date of enrollment.

Response: In consideration of the supportive comments, we are finalizing this provision as proposed. However, we wish to address the recommendation regarding an exception to the requirement for developing a comprehensive plan of care within 30 days of the date of enrollment due to extenuating circumstances. We recognize that there may be circumstances, albeit rare, that would prevent a PO from conducting a timely comprehensive assessment for newly-enrolled PACE participants. However, this is a fundamental part of care planning and is key to a PO's ability to fulfill its mission and provide quality care to its participants. Therefore, it is our expectation that POs will comply with the 30-day timeframe in § 460.106(b) and make every effort to conduct timely assessments in order to develop and begin to implement the individualized plan of care in a timely manner. In those rare situations in which the circumstances prevent a timely assessment, and development of a plan of care, the PO is expected to document the specific circumstances and detail the steps taken to provide immediate care as needed and complete the assessment and plan of care as soon as feasible given the circumstances.

H. Subpart G—Participant Rights

1. Specific Rights to Which a Participant Is Entitled (§ 460.112)

Section 460.112 describes the specific rights of PACE participants, including, in paragraph (b)(1), the right to be fully informed in writing of services available from the PO:

- Before enrollment;
- At enrollment; and
- At the time a participant's needs necessitate the disclosure and delivery of such information to allow informed choice.

We proposed to combine paragraphs (b)(1)(i) and (b)(1)(ii) into proposed paragraph (b)(1)(i) to state that information about PACE services will be provided ''prior to and upon enrollment'' in the PO, and to redesignate current paragraph (b)(1)(iii) as paragraph (b)(1)(ii), in an effort to simplify the language and regulatory construction.

Section 460.112(b)(3) states that each participant has the right to examine, or upon reasonable request, to be assisted in examining the results of the most recent review of the PO conducted by CMS or the SAA and any plan of correction in effect. We proposed to make a technical change to § 460.112(b)(3) by deleting the language ''to be assisted'' and replacing it with ''to be helped.'' The changes to § 460.112(b) are not substantive in nature but are intended to simplify the regulatory language.

Sections 1894(c)(5)(A) and 1934(c)(5)(A) of the Act provide that participants must be permitted to voluntarily disenroll from PACE without cause at any time. Accordingly, § 460.112(c)(3) states that each PACE participant has the right to disenroll from the program at any time. We explained in the proposed rule that we have operationalized this requirement by allowing participants to provide notice of voluntary disenrollment at any time and making that disenrollment effective on the first day of the month after the PO receives the notice. Consistent with our current practice, we proposed to revise paragraph (c)(3) to state that the participant has the right to disenroll from the program at any time and have such disenrollment be effective the first day of the month following the date the PO receives the participant's notice of voluntary disenrollment as set forth in § 460.162(a). As discussed in the proposed rule (81 FR 54686) and section III.J.5. of this final rule, we proposed a corresponding revision to § 460.162 that would state, in a new paragraph (a), that a voluntary disenrollment is effective on the first day of the month following the date the PO receives the participant's notice of voluntary disenrollment. We explained in the proposed rule that, because POs receive a monthly capitation payment from Medicare and/or Medicaid in advance, we effectuate the disenrollment at the end of the capitated payment period.

We received no comments on our proposed revisions to § 460.112, and therefore, we are finalizing this provision as proposed.

2. Explanation of Rights (§ 460.116)

Section 460.116 sets forth requirements for POs with respect to explanation of rights, such as having written policies and procedures on these rights, explaining the rights, and displaying the rights. Section 460.116(c)(1) provides that the PO must write the participant rights in English and in any other principal languages of the community. Consistent with the

proposal regarding marketing materials under § 460.82(c)(1), discussed in section III.F. of this final rule, we proposed to specify that if a state has not established a standard for making the principal language determination, a principal language of the community is any language spoken in the home by at least 5 percent of the individuals in the PO's service area. As we explained in the proposed rule, we established a similar 5 percent language threshold for marketing materials in the MA program (§ 422.2264(e)), and we believed this threshold is also appropriate for PACE because of the similarities in population make-up between the MA program and PACE. Moreover, we noted in the proposed rule, we strive to create harmony across program requirements when feasible. This reduces complexity for those organizations that operate multiple programs.

Section 460.116(c)(2) states that the PO must display the participant rights in a prominent place in the PACE center. We proposed to add the word ''PACE'' before the words ''participant rights'' to specify that participant rights specific to PACE must be displayed. We explained in the proposed rule that during CMS audits of POs, we have observed that POs have displayed rights pertaining to the adult day center or other rights, and not those specific to the PACE program, in the PACE center. As proposed, the language would explicitly state that the PACE participant rights must be posted in the PACE center. We received no comments on our proposed changes to § 460.116, and therefore, we are finalizing the changes as proposed.

3. PACE Organization's Appeals Process (§ 460.122)

Section 460.122 sets forth the requirements for a PO's appeals process. Section 460.122(c)(1) states that a PO's appeals process must include written procedures for timely preparation and processing of a written denial of coverage or payment as provided in § 460.104(c)(3). In the 2006 final rule, we redesignated paragraph (c)(3) to paragraph (d) in § 460.104, but we inadvertently did not make the corresponding change to the citation referenced in § 460.122(c)(1) (71 FR 71292, 71336, and 71337). Therefore, we proposed to amend § 460.122(c)(1) to provide the correct citation reference to the standards for a written denial notice by changing it from § 460.104(c)(3) to § 460.104(d)(2)(iv).

We did not receive any comments on our proposed technical change to § 460.122(c)(1). Therefore, we are finalizing this provision as proposed.

I. Subpart H—Quality Assessment and Performance Improvement

As discussed in section III.A. of this final rule, to update the terminology to comport with that used in other CMS programs, we proposed to replace all references to ''quality assessment'' and ''performance improvement'' with ''quality improvement'' throughout part 460, including the heading for subpart H and the titles of various sections. In this section, we discuss the other changes that we proposed to subpart H.

1. General Rule (§ 460.130)

Sections 1894(e)(3)(B) and 1934(e)(3)(B) of the Act require that, under a PACE program agreement, the PO, CMS, and the SAA shall jointly cooperate in the development and implementation of health status and quality of life outcome measures with respect to PACE participants. Section 460.130 requires a PO to develop, implement, maintain, and evaluate a quality assessment and performance improvement program, which reflects the full range of services furnished by the PO. Further, a PO must take actions that result in improvement in its performance in all types of care.

Section 460.140 refers to additional quality assessment activities related to reporting requirements. We proposed to move the requirement in § 460.140 to § 460.130 as new paragraph (d), so that all of the general rules for quality improvement would be part of the first section in subpart H. As we noted in the proposed rule, this change would leave no requirements under § 460.140, so we also proposed to remove § 460.140.

2. Quality Assessment and Performance Improvement Plan (§ 460.132)

Section 460.132 sets forth our current requirements with respect to a Quality Assessment and Performance Improvement (QAPI) plan. We proposed to revise the requirements for a QAPI plan in § 460.132. In addition to the terminology change that we discussed previously (replacing all references to ''quality assessment and performance improvement'' with the term ''quality improvement''), we proposed to revise paragraph (a) to require a PO to have a written quality improvement plan that is collaborative and interdisciplinary in nature. As we explained in the proposed rule, the PACE program is unique in its structure in that it has a collaborative and interdisciplinary approach in treatment of PACE participants. We stated that we believed a PO's quality improvement plan should reflect this collaboration and interdisciplinary approach in its improvement goals. That is, any time the PO's governing body develops a plan of action to improve or maintain the quality of care, the plan should focus on the collaborative and interdisciplinary nature of the PACE program. For example, a PO may identify as a goal the need to improve its organization's overall fall incident rate, and develops a plan of action to address this need that involves soliciting recommendations concerning this issue from its staff and contracted resources (for example, pharmacists, physicians, social workers, transportation providers, and PTs). This plan of action is collaborative because it involves input from staff and IDT members with experience and knowledge, and it is interdisciplinary because those individuals have different skills, levels of education and professional backgrounds and different perspectives on how to improve the fall rate. We explained in the proposed rule that we believed requiring a collaborative and interdisciplinary quality improvement plan will help POs identify and improve PACE quality issues more appropriately. Therefore, we proposed to revise paragraph (a) to require a PO to have a written quality improvement plan that is collaborative and interdisciplinary in nature.

3. Additional Quality Assessment Activities (§ 460.140)

As discussed in section III.I.1. of this final rule, we proposed to redesignate the content of § 460.140 to § 460.130, and therefore, we proposed to remove § 460.140.

The following is a summary of the public comments we received on the proposed changes to the quality requirements in subpart H and our responses to comments.

Comment: We only received comments on the proposed revision to § 460.132. The many comments we received were all in favor of the proposed revision. Commenters believed that the term ''collaborative and interdisciplinary in nature'' accurately describes the quality improvement plans that POs have under the current requirements. One commenter recommended that CMS also require POs to solicit ongoing collective input from individuals and their families and caregivers when developing quality improvement plans. Another commenter urged CMS to put additional protections in place to ensure that any quality improvement plan is comprehensive and accounts for care provided across the ''care'' continuum and in various settings.

Response: We appreciate the comments and are finalizing the

modifications to § 460.132 and the other changes to subpart H as proposed. Regarding the two recommendations we received on quality improvement plans, we will take this input into account as we consider future subregulatory guidance or rulemaking on PACE quality requirements.

J. Subpart I—Participant Enrollment and Disenrollment

1. Eligibility to Enroll in a PACE Program (§ 460.150)

In accordance with sections 1894(a)(5) and (c)(1) and 1934(a)(5) and (c)(1) of the Act, we established § 460.150 to specify the requirements for eligibility to enroll in a PACE program.

Section 460.150(c)(1) provides that, at the time of enrollment, an individual must be able to live in a community setting without jeopardizing his or her health or safety, and § 460.150(c)(2) states that the eligibility criteria used to determine whether an individual's health or safety would be jeopardized by living in a community setting must be specified in the program agreement. As we explained in the proposed rule (81 FR 54687) and the 2006 final rule (71 FR 71309), determining whether an individual's health or safety would be jeopardized by living in the community involves assessing the individual's care support network, as well as the individual's health condition. This assessment is done by the PO based upon criteria established by the state and specified in the PACE program agreement. We proposed to codify this longstanding policy in our regulations by revising § 460.150(c)(2) to include a reference to the SAA criteria used to determine if an individual's health or safety would be jeopardized by living in a community setting, to indicate that these criteria are developed by the SAA.

A discussion of the public comments we received on this proposal, and our responses to those comments, appears below.

Comment: Several commenters expressed support for our proposal to codify the longstanding policy of using criteria developed by the SAA to determine if an individual's health or safety would be jeopardized by living in a community setting. Another commenter recommended that we develop a new PACE eligibility criterion for individuals who are institutionalized but have a realistic potential to return to their homes. Another commenter requested that CMS work with states to ensure that SAA criteria are sufficiently clear, so as to ensure consistent application.

Response: We thank the commenters for their support. We did not propose any additional criteria for PACE eligibility, and therefore, we believe the comment regarding development of a new PACE eligibility criterion is outside of the scope of this regulation. With regard to the request for us to work with states to ensure that the SAA criteria they develop are clear, we believe that since the states are responsible for developing the criteria, it is also the states' responsibility to ensure the criteria are sufficiently clear.

Comment: One commenter requested that in developing the final rule we take into consideration the systems and protocols implemented by states to process PACE eligibility determinations and that we allow for flexibility in our requirements and accommodate the various state protocols, some of which may provide beneficiary protections in addition to what CMS requires.

Response: We did not propose any changes to the requirements for determining eligibility for PACE, and therefore, we believe this comment is outside of the scope of this regulation. We are finalizing this provision as proposed.

2. Enrollment Process (§ 460.152)

Section 460.152 specifies the PO's responsibilities during the intake process and actions required in the event a potential PACE participant is denied enrollment because his or her health or safety would be jeopardized by living in a community setting. Section 460.152(b)(4) states that the PO must notify CMS and the SAA if a prospective participant is denied enrollment because his or her health or safety would be jeopardized by living in a community setting and make the documentation available for review. We proposed to add language to paragraph (b)(4) to require that such notification be in the form and manner specified by CMS, as this would reflect our current practice of requiring POs to provide these notifications to CMS and the SAA electronically.

We received no comments on our proposal to require that notification to CMS and the SAA be in the form and manner specified by us; therefore, we are finalizing this provision as proposed.

3. Enrollment Agreement (§ 460.154)

Section 460.154 specifies the general content requirements for the enrollment agreement. Section 460.154(i) states that the enrollment agreement must contain a notification that enrollment in PACE results in disenrollment from any other Medicare or Medicaid prepayment plan or optional benefit. It further provides that electing enrollment in any other Medicare or Medicaid prepayment plan or optional benefit after enrolling as a PACE participant is considered a voluntary disenrollment from PACE. We explained in the proposed rule that we were concerned about possible misinterpretations of this provision, and therefore, we proposed to add language to paragraph (i) to state that if a Medicaid-only or private pay PACE participant becomes eligible for Medicare after enrollment in PACE, he or she will be disenrolled from PACE if he or she elects to obtain Medicare coverage other than from his or her PO.

A discussion of the public comment we received on this proposal, and our response to this comment, appears below.

Comment: One commenter expressed support for our proposal and urged us to ensure that messaging regarding the potential for disenrollment be clear and easy to understand in PACE participant materials.

Response: We thank the commenter for its support. We will take the suggestion regarding clear messaging into consideration when developing additional subregulatory guidance on PACE disenrollment and beneficiary protections. We are finalizing this provision as proposed.

4. Other Enrollment Procedures (§ 460.156)

Section 460.156 specifies the documentation and information that a PO must provide to a PACE participant who signs an enrollment agreement, as well as to CMS and the SAA. Sections § 460.156(a)(2) and § 460.156(a)(4) state that, after the participant signs an enrollment agreement, the PO must give the participant a PACE membership card and stickers for his or her Medicare and Medicaid cards, as applicable, which indicate that he or she is a PACE participant and include the phone number of the PO, respectively. We proposed to delete the sticker requirement currently at § 460.156(a)(4) and revise the PACE membership card requirement at § 460.156(a)(2) so the PO would give the participant a PACE membership card that indicates that he or she is a PACE participant and that includes the phone number of the PO. As we noted in the proposed rule, this would not only ensure that the participant's Medicare and Medicaid cards are not damaged if stickers are removed in the event the participant disenrolls from PACE, but also would save participants from having to carry their Medicare and Medicaid cards with them, a practice we generally discourage

based on the risk that a beneficiary's personal information may be lost or exposed.

A discussion of the public comments we received on this proposal, and our responses to those comments, appears below.

Comment: Commenters were generally supportive of our proposal to delete the sticker requirement and revise the PACE membership card requirement. One commenter stated that this change may result in POs having to reissue all PACE membership cards, which could impose additional administrative burdens on the POs.

Response: We appreciate the commenters' support for this change. With regard to the potential for additional administrative burden, we note that this change relieves POs of the requirement to produce and distribute additional materials (that is, the stickers) for participants' Medicare and Medicaid cards. Moreover, POs are already required to provide PACE membership cards. While the new requirement to include the PO's phone number on the PACE membership card will affect some POs that do not currently include contact information on their cards, we believe most POs include this information already. Further, the elimination of the sticker requirement will lessen ongoing burden and costs for POs. Therefore, we are finalizing this provision without modification.

Comment: One commenter requested that CMS revise the enrollment effective date requirement in § 460.158 to enable enrollment to become effective on the date of the signed enrollment agreement. The commenter stated that the current enrollment period (effective the first day of the calendar month following the date of the executed enrollment agreement) causes delays in obtaining PACE services and PACE participant and family dissatisfaction.

Response: Consistent with the PACE Protocol (64 FR 66300), we established in § 460.158 that a participant's enrollment in the program is effective the first day of the calendar month following the date the PO receives the signed enrollment agreement. We did not propose any changes to § 460.158 in the proposed rule, and therefore, we believe this comment about revising the enrollment agreement effective date is outside the scope of this rule. In addition, we note that enrollment of individuals and payment to POs is based on whole calendar months. In other words, Medicare and Medicaid capitation payments are paid to a PO for an entire month and are not pro-rated. Medicare and Medicaid capitation payment in whole month increments is consistent with the requirement that enrollment in a PO is always effective on the first calendar day of a month and disenrollment is always effective on the last calendar day of a month. Given that both enrollment and Medicare and Medicaid payment occur in whole month increments, we would be unable to accommodate such a request for a change to § 460.158.

5. Voluntary Disenrollment (§ 460.162)

In accordance with sections 1894(c)(5)(A) and 1934(c)(5)(A) of the Act, § 460.162 states that a PACE participant may voluntarily disenroll without cause from the program at any time. We proposed to retain this language in new paragraph (b) and add new paragraphs (a) and (c). As described previously in our discussion of proposed changes to § 460.112(c)(3), we have operationalized the statutory requirements regarding voluntary disenrollment by allowing participants to provide notice of voluntary disenrollment at any time and making that disenrollment effective on the first day of the month after the PO receives the notice. To align with the proposed changes in § 460.112(c)(3) and our current practices for Medicare health plan disenrollment, in paragraph (a), we proposed to add language stating that a participant's voluntary disenrollment is effective on the first day of the month following the date the PO receives the participant's notice of voluntary disenrollment.

Sections 1894(c)(5)(A) and 1934(c)(5)(A) of the Act state that enrollment and disenrollment of PACE program eligible individuals in a PACE program must be under regulations and the PACE program agreement with certain statutory restrictions. Moreover, sections 1894(b)(1)(A)(i) and 1934(b)(1)(A)(i) of the Act state that, under the PACE program agreement, a PO must provide all items and services covered under titles XVIII (Medicare) and XIX (Medicaid). As we stated in the proposed rule, through record review during on-site audits and follow-up regarding family or participant grievances and complaints, we have encountered some instances in which a participant needed additional services and was encouraged to voluntarily disenroll by either an employee or a contractor of the PO in an effort to reduce costs for the PO. To help prevent this practice, we proposed to affirmatively require at § 460.162(c) that POs ensure their employees or contractors do not engage in any practice that would reasonably be expected to have the effect of steering or encouraging disenrollment of PACE participants due to a change in health status. We noted in the proposed rule that, under § 460.40(c), a PO would be subject to sanctions for engaging in this type of behavior—that is, discriminating in disenrollment among Medicare or Medicaid beneficiaries on the basis of an individual's health status or need for health care services.

A discussion of the public comments we received on our voluntary disenrollment proposals, and our responses to those comments, appears below.

Comment: One commenter requested that we create an exception to the voluntary disenrollment effective date for participants electing the Medicare hospice benefit and allow voluntary disenrollments for those individuals to be effective prior to the first day of the month following the date the PO receives the participant's notice of voluntary disenrollment. The commenter stated that the current requirement may delay the start of hospice services and can lead to dissatisfaction for participants and their family members.

Response: Enrollment of individuals and payment to POs is based on whole calendar months. In other words, Medicare and Medicaid capitation payments are paid to a PO for an entire month and are not pro-rated. Medicare and Medicaid capitation payment in whole month increments is consistent with the requirement that enrollment in a PO is always effective on the first calendar day of a month and disenrollment is always effective on the last calendar day of a month. Given that both enrollment and Medicare and Medicaid payment occur in whole month increments, we are unable to accommodate the request for an exception for participants electing the Medicare hospice benefit. Therefore, we are finalizing the proposed change to § 460.162(a) without such an exception.

Comment: Several commenters opposed the proposal to revise § 460.162 to specify that a participant's voluntary disenrollment is effective on the first day of the month following the date the PO receives the participant's notice of voluntary disenrollment. The commenters requested that we retain the current regulation, which simply states that a PACE participant may voluntarily disenroll from the program without cause at any time. One commenter expressed concern that states' enrollment and disenrollment systems may not allow for disenrollment from a PACE program to be effective the first day of the following month if notice is given beyond a certain day of the

month. This commenter stated that while it is possible to disenroll a Medicare-only beneficiary effective the first day of the month following notification, disenrollment of Medicaid-only and dual-eligible PACE participants involves states' Medicaid systems, which may require notification to be provided in advance of a ''cutoff date'' in order for a disenrollment to be effective the first day of the following month. In these situations, the commenter stated, disenrollment requests received from Medicaid-only and dual-eligible PACE participants after a cutoff date may be delayed until the first day of the second month following receipt.

Response: We note that sections 1894(c)(5)(A) and 1934(c)(5)(A) of the Act state that PACE participants shall be permitted to voluntarily disenroll without cause at any time. After carefully considering the commenters' concerns, we respectfully disagree that concerns about state enrollment and disenrollment systems outweigh the need to protect participants by requiring POs to effectuate participant requests for disenrollment from the PO in an expeditious manner. While we appreciate the commenter's concern about state systems, we believe that it would be inappropriate to require that some PACE participants who wish to leave PACE remain enrolled for an additional month because of the inability of a state Medicaid agency to react to the participant's request in a timely manner. Delaying the effective date of a valid disenrollment request should not be the course of action when a participant's request for disenrollment is received toward the end of a month. We also note that imposing an early cutoff date creates unnecessary delays for participants who do not have Medicaid, even though the processing of their request does not involve any of the state systems issues described by the commenter. We believe establishing a policy of differing disenrollment effective dates based on PACE participants' eligibility for Medicaid and when they choose to submit the disenrollment request to the PO, would be challenging for POs to successfully implement and potentially confusing to participants. We also believe it would result in inequitable treatment among PACE participants. We further note that MA organizations and Medicare PDP sponsors have a longstanding requirement to effectuate voluntary disenrollment requests on the first day of the following month, regardless of when the request is received during the month or whether the beneficiary is eligible for Medicaid. We have operationalized this requirement for PACE by allowing participants to provide notice of voluntary disenrollment at any time and making that disenrollment effective on the first day of the month after the PO receives the notice. We believe that Medicare participants who have chosen to receive their Medicare health and drug benefits through PACE, instead of through an MA plan or a Medicare PDP, should not have their disenrollment delayed solely because they submit their request for disenrollment in the latter part of a month.

Comment: One commenter expressed support for the proposed requirement that POs ensure their employees or contractors do not steer or encourage disenrollment of PACE participants due to a change in health status. In addition, this commenter requested that we add ''functional, cognitive, or psychosocial'' as health status changes for which disenrollment should not be encouraged. In support of the comment, the commenter referenced the expansion of the non-discrimination provisions contained within § 460.40(a)(3) to include prohibitions on discrimination on the basis of ''functional, cognitive, or psychosocial status.''

Response: We appreciate the comment and agree that these sections of the PACE regulations should be consistent. However, as we explain in our discussion of § 460.40(a)(3) in section III.E.1 of this final rule, we inadvertently included the reference to ''functional, cognitive, or psychosocial status'' in the proposed rule and have restored the current language in this final rule. While we may consider revising the description of health status in future rulemaking, we are not doing so in this rule, and the reference to ''health status'' will remain in both § 460.40 and § 460.162. Therefore, we are finalizing this proposed change to § 460.162(c) without modification.

6. Involuntary Disenrollment (§ 460.164)

Section 460.164 specifies the conditions under which a PACE participant can be involuntarily disenrolled from a PACE program. The reasons for involuntary disenrollment are derived from sections 1894(c)(5)(B) and 1934(c)(5)(B) of the Act, additional statutory requirements (for example, the PACE program agreement is not renewed, or the participant no longer meets the state Medicaid nursing facility level of care requirements), and the PACE Protocol. We proposed to redesignate paragraphs (a) through (e) as paragraphs (b) through (f) and to add new paragraph (a) that specifies that a participant's disenrollment occurs after the PO meets the requirements in this section and is effective on the first day of the next month that begins 30 days after the day the PO sends notice of the disenrollment to the participant. For example, if a PO sends a disenrollment notice on April 5, the disenrollment would be effective June 1–30 days after April 5 is May 5, and the first day of the next month after May 5 is June 1. We proposed to add this requirement to make it clear when a participant's involuntary disenrollment is effective. Additionally, we proposed to add this requirement to protect participants' due process, as our regulations and guidance do not currently include an advance notice requirement. We noted in the proposed rule that the PO must not send the disenrollment notice until the SAA has reviewed the involuntary disenrollment and determined that the PO has adequately documented acceptable grounds for disenrollment, as required by current paragraph (e) (proposed paragraph (f)). We stated that we believed 30 days would provide sufficient time for an individual to gather documentation, medical records, or other information in order to respond to the PO's proposed disenrollment action, should he or she disagree. Without the 30 days of advance notice, we noted in the proposed rule, a PO could notify a participant about an involuntary disenrollment late in the month and make the effective date of the involuntary disenrollment the first day of the following month, only a few days later. This would not allow sufficient time for a participant to contest the disenrollment or to effectively coordinate a transition to other care and services.

Section 460.164(a) currently states the reasons a participant may be involuntarily disenrolled from PACE. Paragraph (a)(1) states that the PO may involuntarily disenroll a participant for failing to pay, or to make satisfactory arrangements to pay, any premium due the PO after a 30-day grace period. As noted previously, we proposed to redesignate (a)(1) as (b)(1) and restructure the sentence to clarify that the 30-day grace period applies to both failure to pay and failure to make satisfactory arrangements to pay any premium due the PO. We explained in the proposed rule that we proposed the change because we believed the current sentence structure creates confusion as to whether the grace period applies to both payment of the premium ''and'' making satisfactory arrangements to pay. We noted that the revision would

clarify that an involuntary disenrollment cannot be initiated due to a participant's failure to pay until after a 30-day grace period for the participant to pay or to make satisfactory arrangements to pay. Satisfactory arrangements could be, for example, a participant's agreement to pay through installments, or agreement to pay within a specific time period.

We also proposed to redesignate paragraphs (a)(2) to (a)(6) as (b)(4) to (b)(8) and to add two additional reasons for involuntary disenrollment in new paragraphs (b)(2) and (b)(3). In paragraph (b)(2), we proposed new language that would permit involuntary disenrollment if the participant, after a 30-day grace period, fails to pay or make satisfactory arrangements to pay any applicable Medicaid spend-down liability or any amount due under the post-eligibility treatment of income processes as permitted under § 460.182 and § 460.184. Section 1934(i) of the Act, as well as §§ 460.182(c), 460.184, 460.152 and 460.154 pertain to these payment amounts. Under section 1934(i) of the Act and § 460.184(a), a state may provide for post-eligibility treatment of income for participants in the same manner as a state treats post-eligibility income for individuals receiving services under a Medicaid waiver under section 1915(c) of the Act. Section 460.182(c)(1) requires that the PO accept the Medicaid capitation payment as payment in full ''except'' for payment with respect to spend-down liability and post-eligibility treatment of income. Section 460.152(a)(1)(iv) and (v) requires that PACE staff explain specific information to the potential participant and his or her representative or caregiver, including any Medicaid spend-down obligation and post-eligibility treatment of income. Section 460.154(g) requires that a participant who is Medicaid eligible or a dual eligible be notified and required to acknowledge in writing that he or she may be liable for any applicable spend-down liability and amount due under the post-eligibility treatment of income process. We explained in the proposed rule that, operationally, a PO needs the ability to involuntarily disenroll participants based on nonpayment of these amounts. We noted that participants are obligated to pay these amounts as part of the PO's overall reimbursement for care and services provided through the program. Moreover, we stated that we understood that a participant's failure to pay these amounts can have a significant financial impact on the PO. Continued insufficient reimbursement to the PO on an ongoing basis could affect the PO's financial viability and its ability to continue operations. We explained that we have previously addressed this issue for many POs through approval of waivers, but we believed addressing it through a regulatory change is more efficient and is permitted under the PACE statutory authority. Moreover, we noted, as with any involuntary disenrollment, an involuntary disenrollment based on nonpayment of applicable Medicaid spend-down liability or any amount due under the post-eligibility treatment of income process must be reviewed by the SAA to determine that the PO has adequately documented acceptable grounds for disenrollment before it becomes effective.

In paragraph (b)(3), we proposed to add language that would permit involuntary disenrollment in situations where the participant's caregiver engages in disruptive or threatening behavior. We also proposed to redesignate current paragraphs (b)(1) and (b)(2) as paragraphs (c)(1)(i) and (c)(1)(ii), respectively, and to add new paragraph (c)(2) to describe what we consider to be disruptive or threatening behavior of a participant's caregiver.

Specifically, we proposed that a PACE participant may be involuntarily disenrolled from the PO if a participant's caregiver engages in disruptive or threatening behavior that jeopardizes the participant's health or safety, or the safety of the caregiver or others. We noted in the proposed rule that this would include any family member involved in the participant's care. We stated that we believed sections 1894(c)(5)(B) and 1934(c)(5)(B) of the Act, which state that a PO may not disenroll a participant except for engaging in disruptive or threatening behavior, as defined in such regulations (developed in close consultation with SAAs), could be read to include a caregiver. We also noted that the PACE Protocol listed as a basis for involuntary disenrollment that the participant ''experiences a breakdown in the physician and/or team-participant relationship such that the PO's ability to furnish services to either the participant or other participants is seriously impaired,'' which we believed could include disruptive or threatening behavior of a caregiver (64 FR 66300).

We explained in the proposed rule that, although we previously stated in the 2006 final rule (71 FR 71316) that we would not include as a basis for disenrollment the disruptive or threatening behavior of family members that are involved in the participant's care, as we gained more experience with PACE, we realized that it is not always possible for a PO to establish alternative arrangements that would not disrupt the PO's ability to provide adequate services to the participant in situations where the caregiver is engaging in threatening or disruptive behavior. We noted in the proposed rule that, given the variety of settings in which POs provide services, including the PACE center and the participant's home, there may be situations where the caregiver's disruptive or threatening behavior jeopardizes the health or safety of the participant, other PACE participants, staff, or visitors and it is not be feasible to establish alternative arrangements. We stated that we have already approved waivers for involuntary disenrollment, several of which address disruptive or threatening caregiver behavior. The requests for waivers have come from POs that have experienced situations in which their ability to safely and effectively care for participants is potentially compromised by the behavior of the participant's caregiver that jeopardizes the health or safety of others including other participants, staff, or visitors. We noted in the proposed rule that the proposed revision would obviate the need for those waivers, thereby reducing the burden on POs, states, and CMS.

We emphasized in the proposed rule that a PO must only pursue involuntary disenrollment of a participant based on a caregiver's behavior after it has engaged in efforts to resolve the situation and has documented all of those efforts. As set forth in current paragraph (e) (proposed paragraph (f)), all involuntary disenrollments require a review and final determination by the SAA before they can become effective, so as to ensure that the PO has adequately documented acceptable grounds for disenrollment. As set forth in § 460.168, when a PACE participant is disenrolled from the PO, the PO must facilitate a participant's enrollment into other Medicare or Medicaid programs for which the participant is eligible and must make sure medical records are available to the new providers. We explained in the proposed rule that this will help ensure that the participant receives needed care. We noted that we did not propose a similar change to § 460.164(b)(2) (proposed paragraph (c)(2)), which refers to involuntary disenrollment of a participant with decision-making capacity who consistently refuses to comply with his or her individual plan of care or the terms of the PACE enrollment agreement. A PO cannot involuntarily disenroll a participant based on the

caregiver's noncompliance with the participant's plan of care or terms of the PACE enrollment agreement.

A discussion of the public comments we received on our involuntary disenrollment proposals, and our responses to those comments, appears below.

Comment: Two commenters expressed support for our proposed clarification of the effective date of an involuntary disenrollment and the new proposed requirement for advance notice of the disenrollment. Another commenter expressed general support for these proposals but requested that we waive the 30-day advance notice requirement when a PACE participant is out of the PO's service area for more than 30 days without giving prior notice to the PO or obtaining approval from the PO.

Response: We appreciate the commenters' support for our proposals; however, we do not believe it would be appropriate to waive the advance notice requirement in circumstances where a participant is out of the PO's service area for a specified time period. We believe the proposed requirement to notify a participant in advance of the PO's decision to involuntarily disenroll the participant is an important protection for all participants, and while we agree that a participant's temporary absence from the service area may raise coverage challenges, we are concerned the lack of advance notice would result in some erroneous disenrollments, given that the participant may not have an opportunity to address any misunderstanding as to the participant's location before the disenrollment takes effect. In the absence of a requirement for advance notice, a PO potentially could issue a disenrollment notice on the last day of month and effectuate the disenrollment the next day. We also note that beneficiaries enrolled in MA plans, Medicare PDPs and Medicare cost plans are provided advance notice of an involuntary disenrollment. We believe that Medicare participants who have chosen to receive their Medicare health and drug benefits through PACE, instead of through an MA plan, Medicare PDP, or Medicare cost plan should have the same protection that advance notice of involuntary disenrollment affords.

Comment: One commenter recommended that CMS consider incorporating into the PACE regulations the grievance and appeals processes available to Medicaid managed care beneficiaries in involuntary disenrollment situations.

Response: While there are some similarities between the regulatory requirements for Medicaid managed care and PACE, they are not completely aligned with regard to how grievances and appeals are defined. We have established specific requirements for PACE regarding grievances (defined in § 460.120 as a complaint expressing dissatisfaction with service delivery or the quality of care furnished) and appeals (defined in § 460.122 as a participant's action taken with respect to the PO's noncoverage of, or nonpayment for, a service). Moreover, we have specified the limited reasons that a participant may be involuntarily disenrolled from PACE in § 460.164, and we require that before an involuntary disenrollment is effective, the SAA must review and determine in a timely manner that the PO has adequately documented acceptable grounds for the disenrollment. The state must provide an appeal avenue for both Medicaid and non-Medicaid participants related to involuntary disenrollments. Since Medicare-only participants do not have access to the State Fair Hearings process, states must develop an administrative review process for PACE participants who are not eligible for Medicaid to address appeals of involuntary disenrollments. And while the PACE regulations do not require the PO to establish an appeal process for an involuntary disenrollment, they are not prohibited from doing so. Because PACE already requires prior state review of a proposed involuntary disenrollment, as well as an avenue of resolution in response to a PO's action to involuntary disenroll a participant, we do not believe it is necessary to incorporate additional protections based on Medicaid managed care requirements.

Comment: One commenter expressed concern about the potential for POs to involuntarily disenroll participants considered ''difficult to serve'' based on the actions of their caregivers. However, the commenter noted that its concerns are mitigated by the expanded anti-discrimination protections proposed in § 460.40. The same commenter stated that PACE participants should not be held responsible for the actions of their caregivers unless the participant is involved to some extent in the disruptive behavior. Two commenters requested that we provide guidance to POs for instances in which a caregiver's behavior is viewed as potentially jeopardizing the health or safety of the participant, or the safety of others. Another commenter opposed involuntary disenrollment based on caregiver behavior, viewing such action as punitive to the participant and creating the potential for adverse health and safety issues. This commenter requested that POs be directed to find alternative arrangements instead of disenrolling the participant.

Response: We do not believe that involuntary disenrollment based on the disruptive behavior of a caregiver or family member should be contingent upon the involvement or encouragement of the participant. Due to the type of individual eligible for and enrolled in a PO (that is, frail elderly meeting a nursing home level of care) and the type of services needed, there is a greater prevalence of involvement by caregivers in most aspects of the participant's care. In addition, there may be participants who are entirely dependent on a caregiver or family member to obtain or arrange for care or services, leading to a greater potential for disruptive or threatening behavior on the part of the caregiver that hinders the PO's ability to provide services to the participant or to others or potentially jeopardizes the health or safety of the participant, or the safety of others. We believe such instances, while rare, may necessitate the involuntary disenrollment of the participant for the safety of the participant, the caregiver or others. We note that all PO requests for involuntary disenrollment due to disruptive or threatening behavior are reviewed for appropriateness by the SAA prior to the disenrollment occurring. We expect the PO to take appropriate action in a manner consistent with the legal requirements applicable to the jurisdictions in which it operates, including state laws relating to mandatory reporting of elder abuse, whenever abuse or neglect of a participant may have occurred. We expect POs to attempt alternative arrangements; however, as we stated in the proposed rule, we understand that is not always possible. We thank the commenters for their concern. Subsequent to the publication of this final rule, we will provide guidance to POs for instances in which a caregiver's behavior is viewed as potentially jeopardizing the health or safety of the participant, or the safety of others.

Regarding the comment referring to expanded anti-discrimination protections, as we discussed previously in sections III.E.1 of this final rule, we inadvertently included a reference to ''functional, cognitive, or psychosocial status'' in § 460.40(a)(3) in the proposed rule, even though our intention was solely to redesignate the paragraph, and we have restored the existing language in this final rule.

Comment: One commenter requested that we establish a process for expedited

SAA review of a PO's request for involuntary disenrollment on the basis of threatening or disruptive behavior and that this process not exceed 30 days. The same commenter suggested that CMS provide advance notice to PACE participants when an involuntary disenrollment request is filed with the SAA and that the PO begin transferring the participant to fee-for-service (that is, non-PACE) providers pending final SAA determination.

Response: We agree that advance notification to participants of the potential for involuntary disenrollment based on caregiver behavior may be helpful; however, we did not propose a new requirement for a notice that would be issued to the participant when the PO submits a request for involuntary disenrollment to the SAA. We also did not propose the creation of a new option for an expedited SAA review of requests for involuntary disenrollment or a new process in which participants are transferred to non-PACE providers prior to the SSA approving the request for involuntary disenrollment. While we believe these recommendations are outside the scope of this rule, we will take these comments under consideration for future subregulatory guidance or rulemaking.

Comment: Commenters were supportive of our proposal to include as a basis for involuntary disenrollment the disruptive or threatening behavior of family members that are involved in the participant's care and involuntary disenrollment based on nonpayment of applicable Medicaid spend-down liability or any amount due under the post-eligibility treatment of income process.

Response: We appreciate the support expressed by the commenters to establish these additional bases for involuntary disenrollment. After considering the comments, we are finalizing those proposed changes, as well as our other involuntary disenrollment proposals without modification.

7. Effective Date of Disenrollment (§ 460.166)

Section 460.166 is currently titled ''Effective date of disenrollment;'' however, it focuses on the PO's responsibilities when disenrolling a participant. Therefore, we proposed to change the title to ''Disenrollment responsibilities'' to better describe the subject of this section.

We received no comments on this proposal, and therefore, we are finalizing it without modification.

8. Reinstatement in Other Medicare and Medicaid Programs (§ 460.168)

Section 460.168 describes the PO's responsibility to facilitate a participant's reinstatement in other Medicare and Medicaid programs after disenrollment. Section 460.168(a) states that a PO must make appropriate referrals and ensure that medical records are made available to new providers in a ''timely manner.'' To ensure POs interpret ''timely manner'' uniformly, we proposed to change ''in a timely manner'' to ''within 30 days,'' which would help ensure a smooth transition for participants. We proposed 30 days because we believed this would balance the need to give the PO adequate time to gather the medical records, make copies, and deliver them to the new providers with the need to ensure that new providers receive the medical records as soon as possible to help ensure a smooth transition for the participant and continued access to medications and other needed ongoing care.

Comment: One commenter expressed support for our proposal to require POs to make appropriate referrals and ensure medical records are made available to new providers ''within 30 days,'' as opposed to in a ''timely manner.'' Another commenter requested that we clarify the actions to which the proposed timeframe refers.

Response: We did not propose any changes to the actions the PO must take to facilitate a participant's reinstatement in other Medicare and Medicaid programs after disenrollment. We believe the actions to which the 30-day timeframe applies are adequately specified in the regulation; just as the current timeliness requirement applies to both making appropriate referrals and ensuring medical records are made available to new providers, the PO will be expected to carry out both of those actions ''within 30 days'' once the final rule takes effect. We are finalizing this provision as proposed.

K. Subpart J—Payment

1. Medicaid Payment (§ 460.182)

Section 1934(d) of the Act requires a state to make prospective monthly capitated payments for each PACE program participant eligible for medical assistance under the state plan. The capitation payment amount must be specified in the PACE program agreement and be less, taking into account the frailty of PACE participants, than the amount that would otherwise have been paid under the state plan if the individuals were not enrolled in a PACE program. As we explained in the proposed rule, there is no national Medicaid rate-setting methodology for PACE; rather, each state that elects PACE as a Medicaid state plan option must develop a payment amount based on the cost of comparable services for the state's nursing facility-eligible population. Generally, the amounts are based on a blend of the cost of nursing home and community-based care for the frail elderly. The monthly capitation payment amount is negotiated between the PO and the SAA and can be renegotiated on an annual basis.

We implemented the PACE statutory requirements for Medicaid payment in § 460.182. Section 460.182(b) states that the monthly Medicaid capitation payment is negotiated between the PO and the SAA and specified in the PACE program agreement, and the amount meets certain criteria set forth in paragraphs (b)(1) through (b)(4). Consistent with the revisions to § 460.32(a)(12), we proposed to revise § 460.182(b) to require that the PACE program agreement contain the state's Medicaid capitation rate or the ''methodology'' for establishing the Medicaid capitation rates. We explained in the proposed rule that as a result of changes to the methods states are using to determine capitation rates, which can result in varied payment based on frailty of the population and performance incentive payments, we have found that specifying the capitation amount in the program agreement is sometimes operationally impractical. Additionally, we noted in the proposed rule, because many states update their PACE Medicaid capitation rates annually based on the state fiscal year, there are operational challenges associated with updating the PACE program agreement appendices to reflect changes to the Medicaid rates. We stated that we believed providing the option of including the state's methodology for calculating the Medicaid capitation payment amount is consistent with the statutory requirement in section 1934(d)(2) of the Act that the program agreement specify how the PO will be paid for each Medicaid participant, and we believed it would result in less burden for POs, states and CMS by eliminating the frequency of updates to the PACE program agreement to reflect the routine changes to the PACE Medicaid capitation rates.

We also proposed to redesignate paragraphs (b)(3) and (b)(4) as paragraphs (b)(4) and (b)(5) and add a new paragraph (b)(3), which would require that the monthly capitation amount paid by the SAA be sufficient and consistent with efficiency, economy, and quality of care. Current paragraph (b)(1) requires that the

Medicaid rate be less than what otherwise would have been paid if the participants were not enrolled in PACE, which in essence establishes an upper bound under which the rate must fall. We explained in the proposed rule that while current paragraph (b)(2) also requires that the rate take into account the comparative frailty of PACE participants, the regulation does not require that the rate be adequate or sufficient to provide the services required under the PACE program for the enrolled population. Since the rate is only required to be less than what would have otherwise been paid by Medicaid outside of PACE, there is no lower bound for the rate. We noted in the proposed rule that we proposed the new language to ensure that the Medicaid rate paid under the PACE program agreement is not only less than what would otherwise have been paid outside of PACE for a comparable population, but is also sufficient for the population served under the PACE program, which we believed means not lower than an amount that would be reasonable and appropriate to enable the PO to cover the anticipated service utilization of the frail elderly participants enrolled in the program and adequate to meet PACE program requirements. We proposed that the monthly capitation amount be consistent with efficiency, economy, and quality of care. We explained in the proposed rule that, by efficiency and economy, we meant that the payment amount must reflect that POs bring more efficiencies to the administration, management and oversight of participant care because they are singularly responsible for all of a participant's care (including acute and long term care services), which in many cases outside of PACE are managed by multiple provider entities. We noted that while the efficiencies of providing and coordinating all of a participant's care can result in lower expenditures as compared to a more fragmented payment system with multiple providers and entities providing different aspects of an individual's care, the Medicaid monthly capitation amount must also enable the PO to ensure participant access to quality care and services to meet the participant's needs. We stated that failure to provide adequate reimbursement to POs could negatively affect participant care through reduced care and service authorizations, as well as limit resources for the PO to promote program goals such as quality of care, improved health, community integration of participants, and cost containment, where feasible.

Additionally, we solicited comments about other rate methodologies we may consider requiring for Medicaid capitation payment amounts for PACE. We requested input to determine whether or not there could be other rate setting methodologies for PACE that are more consistent and competitive with rate setting methodologies used for other programs that provide similar services to similar populations on a capitated basis. We provided as an example that Medicaid rates for many of the state financial alignment demonstrations require actuarially sound rates. We noted, however, that any change to the PACE rate setting requirements would need to ensure that the rates are still less than the amount that would otherwise have been made under the state plan if individuals were not enrolled in PACE and be adjusted to take into account the comparative frailty of PACE enrollees, which is required under section 1934(d)(2) of the Act. We did not propose changes to the rate methodology for Medicaid capitation payments, but we stated that we would use public comment to inform possible future PACE rulemaking concerning Medicaid capitation payments.

The following is a summary of the public comments we received on the proposed provisions regarding Medicaid payment and our responses to comments.

Comment: All commenters supported the proposal to incorporate the state's Medicaid rate methodology *or* the Medicaid rates into the PACE program agreement instead of requiring the actual rates. Most commenters supported the proposal without reservation. However, one commenter stated that while the commenter supports the Medicaid rate methodology proposal, it seems to remove the incentive for the state to negotiate the Medicaid rates in a timely manner.

Response: We appreciate the support for this proposed change. In response to the comment expressing concern that states will have less incentive to update and negotiate their rates in a timely manner, we will take this into consideration when issuing updated guidance to states regarding the Medicaid rate setting process.

Comment: All commenters supported the proposal to add the requirement that Medicaid PACE capitation rates be sufficient and consistent with efficiency, economy and quality of care. However, two commenters recommended that CMS use alternate language instead of ''sufficient'', such as ''reasonable and appropriate'' or ''reasonable, appropriate and attainable'', which is part of the standard in § 438.4(a) for actuarially sound capitation rates in Medicaid managed care. One commenter recommended defining ''sufficient'' in regulation to mean not lower than an amount that would be reasonable and appropriate to enable the PO to cover the anticipated service utilization of the frail elderly participants enrolled in the program and adequate to meet PACE program requirements. Two commenters also requested details or guidance on how the ''lower bound'' would be calculated. Two commenters suggested requiring sufficient language in the rate method description to enhance transparency of the Medicaid rate setting process. Two commenters recommended requirements to ensure Medicaid rates take into account the full financial risk for all Medicaid covered services, including nursing home care, without a restriction or adjustment for length of stay. One commenter recommended that the final rule promote use of experience and risk based methodologies in general, and support state flexibility in tailoring rate setting methods to reflect state circumstances. Another commenter recommended allowing direct use of appropriate adjusted experience from Medicaid managed LTC programs in addition to or in place of FFS experience or PACE experience.

Response: We appreciate the overall support for this proposed change. In response to the commenter that recommended we modify language in the final rule to clarify that rates should be actuarially sound, we are not able to require that PACE rates be actuarially sound because actuarially sound rates could exceed the amount that was otherwise paid by the state, if the individuals were not enrolled in PACE, and PACE rates are required by statute to be less than the amount that would have otherwise been paid if participants were not in PACE. In response to the commenters that recommended alternative language to ''sufficient and consistent with efficiency, economy and quality of care'', which is terminology that governs Medicaid fee-for-service payments at section 1902(a)(30)(A) of the Act, and instead recommended language consistent with established standards used in Medicaid managed care, we agree this standard would be more appropriate because PACE as a capitated model is more aligned with Medicaid managed care than Medicaid fee-for-service. In response to commenters' concerns regarding transparency of the state's rate method,

and that rates take into account the full financial risk that POs assume, we will take that into consideration when issuing updated guidance to states regarding the Medicaid rate setting process. In response to the commenter questioning how the ''lower bound'' will be defined, we did not intend to establish or define a specific lower bound for PACE Medicaid rates, but would expect the state to be able to demonstrate that the Medicaid rates comply with regulatory requirements. In response to the comment regarding state use of Medicaid managed LTC experience in development of PACE rates, the current regulation requires that the Medicaid rates be less than the amount that would otherwise been paid under the state plan if the participants were not enrolled in PACE, among other requirements. That amount is not limited to a fee-for-service comparable population, and states are not prohibited from using Medicaid managed care data in determining the amount that would otherwise have been paid, but they must be able to demonstrate that the amount meets the existing PACE requirements. Recognizing that more states will be using managed care experience for their comparable population, we will take that into consideration when issuing updated guidance to states regarding the Medicaid rate setting process in PACE. We appreciate the overall support for the proposed changes. While we are finalizing § 460.182(b) to require that the PACE program agreement contain the state's Medicaid capitation rate or the ''methodology'' for establishing the Medicaid capitation rates, we have decided not to finalize the proposed language that rates be sufficient and consistent with efficiency, economy and quality of care. However, we appreciate all of the comments and feedback and will take this input into account as we consider any changes during future rulemaking.

Comment: Regarding alternative rate methodologies for PACE Medicaid payments, some commenters suggested: Using Grade of Membership methodology to identify a long-term-care admission cohort; permitting a ''tiered'' rate structure that Medicare-only individuals would be required to pay based on services provided under the program; requiring actuarial certification of rates; requiring that rates related to LTSS be consistent across Medicaid and PACE; and that CMS develop a workgroup with stakeholders including the National PACE Association and POs regarding alternate methods for rate setting. Two comments related to the Medicare PACE capitation amounts and suggested: That Medicare rates for POs be consistent with Medicare Medicaid Plans (MMP) or Dual Special Needs Plans (DSNP) to create a level playing field; and that changes to PACE Medicare rates be made to align with MA rules.

Response: We appreciate the feedback provided in response to our request for comments about other rate methodologies that may be applied to PACE Medicaid payments. While we did not propose changes to the rate methodology for Medicaid capitation payments, we will use the public comments received to inform possible future PACE rulemaking concerning Medicaid payment. We did not propose any changes to the Medicare payment requirements under § 460.180, and therefore, we believe the recommendations for changes to the Medicare PACE rates are outside of the scope of this rule.

L. Subpart K—Federal/State Monitoring

1. Monitoring During Trial Period (§ 460.190) and Ongoing Monitoring After Trial Period (§ 460.192)

Sections 1894(e)(4)(A) and 1934(e)(4)(A) of the Act require the Secretary, in cooperation with the SAA, to conduct a comprehensive annual review of the operation of a PO during its trial period in order to assure compliance with the requirements of sections 1894 and 1934 of the Act and PACE regulations. The trial period is defined as the first 3 years of the PO's contract with CMS and the SAA. Sections 1894(e)(4)(A) and 1934(e)(4)(A) of the Act further provide that the review must include: An on-site visit; a comprehensive assessment of the PO's fiscal soundness; a comprehensive assessment of the PO's capacity to provide PACE services to all enrolled participants; a detailed analysis of the PO's substantial compliance with all significant requirements of sections 1894 and 1934 of the Act and PACE regulations; and any other elements the Secretary or the SAA considers necessary or appropriate. Sections 1894(e)(4)(B) and 1934(e)(4)(B) of the Act provide that the Secretary, in cooperation with the SAA, must continue to conduct reviews of the operation of the PO after the trial period as may be appropriate, taking into account the performance level of a PO and compliance of a PO with all significant requirements of sections 1894 and 1934 of the Act and PACE regulations. Sections 1894(e)(4)(C) and 1934(e)(4)(C) of the Act provide that the results of the reviews must be reported promptly to the PO, along with any recommendations for changes to the PO's program, and made available to the public upon request.

Sections 460.190 and 460.192 set forth the requirements for monitoring during and after the trial period, respectively. These regulations currently incorporate requirements from the PACE Protocol that are more specific than those provided in statute, in that § 460.190(b)(1) details specific activities that must occur onsite during the trial period reviews, and § 460.192(b) requires that, after a PO's trial period ends, ongoing reviews be conducted onsite at least every 2 years. We proposed to revise these provisions of the existing regulations.

As we explained in the proposed rule, in the 15 years since the initial PACE regulations were established, the PACE program has flourished and we have gained significant program experience with respect to oversight and monitoring of POs. We noted in the proposed rule that we no longer believed that the activities listed in § 460.190(b)(1)(i) through (b)(1)(v) must be performed while onsite at the PACE location; technology affords us the opportunity to complete these tasks remotely. For example, we have implemented the use of webinar technology in the performance of similar program audits of Medicare Advantage organizations and Part D sponsors. This technology allows the entity being reviewed to provide CMS access to information on its computer systems in real time, in a secure manner. It also allows reviewers to interact with the entity being reviewed and its staff, while not being physically present in the building with them. We stated in the proposed rule that the use of this technology has saved significant resources in travel dollars and staff downtime (experienced while they are traveling). Therefore, we proposed to delete the list of specific activities that may be performed as part of an onsite visit as currently set forth in the paragraphs located in § 460.190(b)(1)(i) through (b)(1)(v).

In addition, we proposed revisions to the language at § 460.190(b)(1) and a new paragraph in § 460.190(b)(2) to more closely mirror the text of statute. We noted in the proposed rule that the proposed language retains the obligation that CMS conduct an onsite visit to observe the PO's operations. However, it affords reviewers the flexibility to conduct other portions of the review remotely. We explained that greater flexibility to conduct portions of the review remotely would allow our reviews of POs to gain some of the same

efficiencies that CMS currently achieves through the use of web-based technologies in other programs. Specifically, we proposed in the revised § 460.190(b)(1) that the trial period review include an onsite visit to the PO, which may include, but is not limited to, observation of program operations, and proposed a separate requirement in the new § 460.190(b)(2) that the trial period review include a detailed analysis of the entity's substantial compliance with all significant requirements of sections 1894 and 1934 of the Act and the PACE regulations, which may include review of marketing, participant services, enrollment and disenrollment, and grievances and appeals. We proposed to retain the language found in current (b)(2), (b)(3), and (b)(4), but proposed to redesignate these as (b)(3), (b)(4), and (b)(5).

Section 460.192(b) of the current regulations establishes the obligation for continued oversight after the trial period, including the requirement for an onsite review of every PO every 2 years. We explained in the proposed rule that as the PACE program has grown, and with it the number of POs, the amount of resources spent conducting both trial period and on-going audits of POs has significantly increased. We stated that we must balance the responsibilities of ensuring that all of our beneficiaries are receiving quality care with our duty to effectively manage our resources and ensure proper oversight over all of the programs we manage. Sections 1893 and 1894 of the Act do not require the current level of monitoring.

Consequently, we noted in the proposed rule that we believed that the frequency of ongoing reviews of POs beyond their trial period should occur based on a risk assessment that takes into account the PO's performance level and compliance with the significant requirements of sections 1834 and 1934 of the Act and the PACE regulations. Therefore, we proposed to delete the language in § 460.192(b) that requires onsite review every 2 years and replace it with that requirement that CMS, in cooperation with the SAA, will conduct reviews of the operations of POs as appropriate, by utilizing a risk assessment as the means of selecting which POs will be audited each year. We stated in the proposed rule that this risk assessment would rely largely on the organization's past performance and ongoing compliance with CMS and state requirements. However, we proposed that the risk assessment also take into account other information that could indicate a PO needs to be reviewed, such as participant complaints or access to care concerns. This would mirror our approach in selecting organizations for audit in other programs such as the MA and Part D programs, which is a data driven, risk-based approach. We noted that this risk assessment would utilize important measures specific to PACE, as determined by us including, but not limited to, length of time between audits, past performance, and other data measures, such as grievances and/or self-reported adverse events, also known as PACE Quality Data, as necessary. We stated that we believe using MA and Part D is an appropriate model on which to base PACE audits, because like in MA and Part D, a PO is responsible for providing a participant's benefits in accordance with our regulations. We also explained that we have discovered through the MA and Part D programs that sponsors have varying degrees of compliance and that auditing organizations based on risk allows CMS to focus on those organizations that require closer scrutiny. Similarly, program experience has shown that POs also have varying degrees of compliance; therefore, we noted that we believed this will be a useful tool in selecting organizations for audit and will allow continued oversight and monitoring in the PACE program, with better targeting of resources based on the relative risk each organization presents.

2. Corrective Action (§ 460.194)

Section 460.194(a) requires a PO to take action ''to correct deficiencies identified during reviews.'' However, as we stated in the proposed rule, there has been some uncertainty as to which circumstances trigger the requirement that a PO take action to correct deficiencies. We proposed to revise this regulation to clarify for POs the range of circumstances under which CMS or the SAAs may identify deficiencies that would require action by the POs to correct those deficiencies. We proposed to change § 460.194(a) to state that a PO must take action to correct deficiencies identified by CMS or the SAA as a result of the following:

- Ongoing monitoring of the PO;
- Reviews and audits of the PO;
- Complaints from PACE participants or caregivers; and
- Any other instance CMS or the SAA identifies programmatic deficiencies requiring correction.

We proposed this change to specify that corrective actions will be required to address deficiencies identified by CMS or the SAA through any of these mechanisms.

3. Disclosure of Review Results (§ 460.196)

As we stated in the proposed rule, PACE participants are a frail and vulnerable population, and we recognized that in some cases they may be unable to fully grasp the nature of our review results and use them to make decisions about their healthcare. Our reviews measure the PO's compliance with a variety of CMS requirements, such as the ability of the PO to deliver medically necessary healthcare and medications to their participants. Currently, the regulations require that POs make their review results available in a location that is readily accessible to their participants, without mention of accessibility to other parties. However, we explained in the proposed rule that we believed that not only participants but also their family members, caregivers, or authorized representatives should have access to that information in order to better inform their decisions about the participants' healthcare. Therefore, we proposed to amend § 460.196(d) to ensure that POs make review results available for examination not just by PACE participants, but by those individuals who may be making decisions about PACE participants' care, such as family members, caregivers and authorized representatives, because we believed they should be fully aware of the PO's performance and level of compliance with statutory and regulatory requirements. We also encouraged POs to make review results available to other potential participants and the public, for example, by releasing a summary of the reports online. We stated in the proposed rule that posting comprehensive review results online would satisfy PO requirements under § 460.196(d).

The following is a summary of the public comments we received on the proposed provisions regarding federal and state monitoring and our responses to comments.

Comment: The majority of commenters supported our proposal to no longer mandate an onsite audit every 2 years for every PO following the 3-year trial period. However, while supportive of our proposal to change how often we audit POs following the trial period, multiple commenters were concerned with allowing POs to go too long without an audit. These commenters thought that CMS should set an outer limit (or maximum length of time) that a PO can go without having an audit. These commenters referenced the frail population in PACE as a reason to ensure that POs get an audit on a regular basis. These commenters

suggested a maximum length of time between audits ranging from 3 to 6 years.

Response: We agree with the commenters that there should be a defined length of time that a PO can go without an audit following the trial period. We do not believe that a maximum time limit needs to be implemented through regulation as it is an internal decision and we need operational flexibility to modify this timeframe when necessary based on how the PACE program changes through the years. Therefore, we intend to implement internal guidelines to ensure that POs are audited with an appropriate frequency, but not modify the proposed regulatory text. Additionally, we believe by utilizing a risk assessment for audit selection, we will be able to appropriately safeguard this frail population by targeting, as often as necessary, those POs that CMS believes may present a higher risk to participants' health and safety.

Comment: A few commenters, although not against us finalizing the proposed regulatory changes to monitoring requirements, urged caution in expanding the time between PACE audits following the trial period. One commenter mentioned that increasing the time between audits would place a heavier burden on SAAs. Another commenter mentioned that if a PO is embarking on an expansion, the frequency of monitoring should increase during this period of expansion.

Response: We appreciate these commenters' concerns. We understand that some SAAs may choose to audit POs more frequently if we decide not to audit a particular PO for a number of years. We believe this is an important part of our partnership with the SAAs, and encourage states to monitor POs as often as they believe necessary. While we may not continue to audit all organizations as frequently after the trial period as we did prior to the implementation of this regulation, we will continue frequent account management monitoring and quality reporting for all POs. We believe that this account management monitoring, along with our risk assessment and audits, will help us maintain an appropriate level of oversight in PACE. We also appreciate the comment regarding audits when POs are embarking on an expansion, and we will retain authority to audit POs more frequently if needed.

Comment: Two commenters expressed concern with reducing the number of onsite audits conducted by CMS after the trial period. One commenter said reducing the number of onsite audits would be eliminating the tools that are proven to work in assessing quality of care. The other commenter suggested that if we audit less frequently, we should collect documentation from the PO more frequently to compensate.

Response: While we understand these commenters' concerns, we are confident that we will still conduct effective oversight over POs even if we no longer require onsite visits at least every 2 years. POs that present a higher risk to participants will still be audited on a more frequent basis. Only those organizations that are assessed to be a lower risk will go longer between reviews. Additionally, while we may audit an organization less frequently, POs are still subject to routine account management monitoring and quality reporting. Additionally, the SAA may audit or monitor POs as they see fit, including requesting documentation from POs between audits.

Comment: Several commenters requested clarification on the risk assessment CMS intends to use to select POs for audits. Commenters encouraged CMS to be transparent in how we select POs, including what performance measures we will be using for the risk assessment. Some commenters wanted confirmation that the risk assessment would not be arbitrary and would utilize reasonable standards. Another commenter wanted clarification on whether the risk assessment would be consistent from region to region. Lastly, one commenter requested that grievances be considered in whatever risk assessment is created.

Response: We appreciate these commenters' questions and comments concerning the risk assessment. We believe that by utilizing a data based risk assessment we will be able to appropriately target POs for audit. While we will strive to be transparent in factors or performance standards we will use for our risk assessment, this is an internal tool that will likely change slightly every year based on what CMS PACE subject matter experts believe is important. At a minimum, this assessment tool will likely review data related to grievances, complaints and access to care and take into account when the PO was last audited. Additionally, the risk assessment will likely include measures related to performance level of the PO and any referrals made by either CMS or the SAA. While we do not intend to publish the exact measures utilized in the risk assessment, we anticipate including information in an annual audit report that will discuss the risk assessment for PO audits at a high level, as well as the POs selected for audit in a given year. The annual report may also include summarized audit results, including, common conditions/findings cited and any audit scores applied based on conditions cited. The annual report will be released by us each year through an HPMS memorandum to the industry.

Comment: We received several comments on our proposed use of technology for conducting audits, specifically using webinars to audit a PO when we would not be onsite for the audit. Most of the commenters expressed support for our proposal to use technology to conduct audits. These commenters warned, however, that while the use of technology is good, POs are small and have limited resources, and reminded us that not all organizations will be equipped to handle webinar audits in the same way.

Response: Since PACE is a direct care model, there are times when audits must be conducted onsite. However, allowing the use of webinar technology would allow us to conduct comprehensive reviews of a PO's ability to provide care and services, through review of participant health records, appeals, grievances, and other key program areas. We recognize that most POs are small, and some do not have the sophisticated electronic systems of some larger organizations. Auditors will work within the systems that POs have when conducting audits.

Comment: One commenter questioned if webinar use would mean that auditors would no longer need remote access to POs' systems, like electronic health records.

Response: While we believe that the use of webinars would reduce the instances where auditors may need remote access to review participant records, there may still be instances where remote access is needed. Among other factors, because POs are direct care models, auditors are sensitive to the amount of time PO staff is required to spend conducting the audit and away from providing care to participants. Therefore, auditors may determine that conducting portions of the audits through remote access, rather than through a webinar, would be more beneficial to the PO and participants.

Comment: One commenter opposed our proposed removal of specific program elements from the regulation that might be reviewed while onsite during the trial period audits, specifically marketing, enrollment and disenrollment procedures, participant services, grievances and appeals.

Response: We appreciate this commenter's concerns, however, the removal of the specific elements from

the regulation text does not mean we will no longer be reviewing those elements, either during the trial period or during routine audits. While we are eliminating the reference to specific portions of the regulation, it remains our intent that audits are comprehensive reviews of a PO's compliance with PACE regulations. A key part of that review will be focused on participant records, and all other services relating to a participant's experience and access to care which may continue include review of marketing, participant services, enrollment and disenrollment procedures, and grievances and appeals.

Comment: One commenter questioned if CMS intends to release a new PACE manual and audit guide after this rule is finalized.

Response: After publication of this final rule, we intend to update the PACE manual to reflect the new rules, including the monitoring section of the manual. The PACE audit protocol (guide) was revised in 2017 and was posted for public comment through the Paperwork Reduction Act process. Following publication of the final rule, both the PACE audit protocol and internal auditor instructions will be assessed and updated as needed. The current PACE audit protocol is available at *https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/PACE_Audits.html.*

Comment: One commenter expressed a concern with for-profit POs, and recommended for-profit organizations should be audited more often than not-for-profit organizations.

Response: For purposes of auditing following the trial period, POs that are selected for audit will be selected using a risk assessment tool that assesses a number of factors related to PACE performance. We do not intend to select POs based on for-profit or not-for-profit status.

Comment: One commenter requested that we make auditors aware of the differences between MA and Part D plans and POs.

Response: We agree that PACE is a unique program as both a payer and direct care provider. PACE auditors are trained to understand the unique nature of the PACE program prior to conducting any audits.

Comment: One commenter encouraged CMS to conduct transparent exit interviews at the conclusion of a PO audit.

Response: We agree that we should always strive to be transparent with our audits, including conducting exit conferences to discuss conditions of non-compliance with the PO prior to auditors concluding the audit. Our audit process was revised in 2017 and the new audit protocol for PACE was approved under the Paperwork Reduction Act approval process. This new audit process includes conducting exit interviews following the CMS audit in order to ensure we are transparent regarding the potential non-compliance noted during the review.

Comment: Multiple commenters were supportive of our proposed revision to the requirements for disclosure of the results of PO reviews. Several of these commenters supported our proposal that POs be responsible for making the review results available for examination in a place that is readily accessible to not only participants, but also their family members, caregivers, and authorized representatives. A few commenters, while supportive of the disclosure requirements, thought CMS should be responsible for posting the results of the review so that all consumers can make an informed decision about their PACE program.

Response: We agree that disclosing audit results to more than just participants is important, particularly for family members, caregivers, and authorized representatives that are responsible for making informed decisions regarding appropriate health care. We appreciate commenters' support for our proposal to require POs to make these disclosures. We also appreciate the benefits of CMS reporting some results at a national level in order to continue promoting improvements across the industry, and allowing participants and others to make informed decisions.

We published our first annual audit report in 2018 which summarized audit results from the 2017 audit year, including common conditions/findings, and provided a general overview of the audit structure. That report is available at *https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/PACE_Audits.html.* As noted previously in this final rule, we anticipate this report will continue to be released to the industry via HPMS annually and will include not only summarized information regarding common conditions, but information specific to individual POs as well, including audit scores.

Comment: Two commenters commented on the format of the disclosed review results. One commenter encouraged CMS to make reports as reader friendly as possible in order to aid participants and family members with understanding the results. The other commenter requested that results be published in a standardized manner to help participants and caregivers understand them.

Response: We agree with the commenters that reports and results should be standardized and in an easily readable format. During our audit redesign, we developed standardized reports and will continue to refine them based on continued audit experience and PO feedback.

Comment: One commenter encouraged CMS to not only disclose audit results publicly, but also create a rating system for POs based on quality measures to help participants and their caregivers in making informed decisions.

Response: We thank the commenter for the suggestion. We believe requiring POs to make audit results available to caregivers will help caregivers, participants and their families make informed decisions about participants' care. While we currently score POs' performance in audits, and publish those scores in an annual report, we do not intend to develop a separate rating system due to the unique nature and structure of POs around the country.

Comment: Several commenters, while supportive of POs disclosing audit results to participants and their families, caregivers, and authorized representatives, were concerned that audit reports are too negative. These commenters stated that by focusing only on a PO's deficiencies, the disclosure of these results skew or bias a participant or a participant's caregiver when making a decision about care. These commenters stated that the disclosure of results should focus on positive aspects of the organization, as well as deficiencies.

Response: We understand the concern presented by these commenters. CMS audits are intended to assess a PO's compliance with PACE regulations and manual guidance. Our audits focus on those areas in the PO that are not in compliance and need corrective action implemented. Our audits also focus on the participant experience and access to care. POs are currently required to make the results of these reviews readily available to participants; however, we believe that it is important that caregivers, family members, and authorized representatives are also able to see these results.

Comment: Some commenters offered their support for our proposed modifications to clarify the circumstances when a PO must take action to correct deficiencies identified by CMS or the SAA.

Response: We appreciate the support for this proposal.

After considering the comments, we are finalizing the changes to the federal and state monitoring requirements as proposed.

M. Subpart L—Data Collection, Record Maintenance, and Reporting

1. Maintenance of Records and Reporting of Data (§ 460.200)

In accordance with sections 1894(e)(3)(A) and 1934(e)(3)(A) of the Act, § 460.200 requires POs to collect data, maintain records, and submit reports, as required by CMS and the SAA. Section 460.200(f)(1) states that a PO must retain records for the longest of the following periods: (i) The period of time specified in state law; (ii) 6 years from the last entry date; or (iii) for medical records of disenrolled participants, 6 years after the date of disenrollment. We proposed to change the requirements in paragraphs (f)(1)(ii) and (iii) from 6 years to 10 years for consistency with the statute of limitations under the False Claims Act (31 U.S.C. 3731(b)(2)). For enrollee records, under § 460.200(f)(1)(ii) and (iii), the 10-year requirements would apply only to records of new and existing enrollees in the PO. We explained in the proposed rule that Medicare Advantage requirements at § 422.504(d), Medicare Part D requirements at § 423.505(d), and other CMS programs' record retention requirements, all conform to the statute of limitations for the discovery of violations under the False Claims Act. We also noted that POs that offer qualified prescription drug coverage currently must comply with the Medicare Part D record retention requirement in § 423.505(d). In addition, we stated that the 10-year record retention policy is also consistent with recordkeeping requirements under the Medicaid Drug Rebate Program (§ 447.510(f)). We proposed to extend the 10-year record retention requirement to all PACE records for consistency with these programs and to ensure we have proper oversight for investigating the complex payment and other relationships associated with delivery of Medicare and Medicaid benefits under the PACE program.

The following is a summary of the public comments we received on the proposed provisions regarding data collection, record maintenance and reporting, and our responses to comments.

Comment: One commenter supported our proposal to change the PACE record retention requirement from 6 to 10 years.

Response: We thank the commenter for its support.

Comment: One commenter requested that CMS require POs to collect and report participant data for several ''sociodemographic'' factors, including age, race, ethnicity, primary language, gender identify, sexual orientation, in connection with PACE quality policies.

Response: We do not currently collect this information from POs, but will take this suggestion into account as we consider future subregulatory guidance or rulemaking on PACE quality requirements.

As a result of the comments, we are making no changes to our proposal and are finalizing the modifications to § 460.200 as proposed.

IV. Provisions of the Final Rule

For the most part, this final rule incorporates the provisions of the proposed rule. Those provisions of this final rule that differ from the proposed rule are as follows:

In section III.C.4. of this final rule, Subpart B—PACE Organization Applications and Waivers, we are clarifying the timeframes for applications at § 460.20(c)(2).

In section III.C.6. of this final rule, we are clarifying the PACE waiver submissions process at § 460.26.

In section III.F.10. of this final rule, we are revising the text to specify expectations for agent/broker training at § 460.82(e)(4).

In section III.G.3. of this final rule, regarding the IDT for PACE participants, we are revising § 460.98(c)(1) to refer to ''primary care, including services furnished by a primary care provider as defined in § 460.102(c) and nursing services''.

In section III.G.3. of this final rule, we are not finalizing our changes to § 460.104(d)(2) as proposed and will maintain the current provision which requires that the appropriate members of the IDT, as identified by the IDT, must conduct the in-person assessment. We are however revising § 460.104(d)(2) to specify that unscheduled reassessments may be performed using remote technology in certain circumstances. Specifically, when a participant or his or her designated representative makes a request to initiate, eliminate or continue a particular service, the appropriate members of the IDT, as determined by the IDT, may use remote technologies to conduct unscheduled reassessments when the IDT determines that the use of remote technology is appropriate and the service request will likely be deemed necessary to improve or maintain the participant's overall health status and the participant or his or her designated representative agrees to the use of remote technology.

In section III.F.3. of this final rule, we are finalizing the provisions related to the compliance oversight program as proposed at § 460.63 in part. We are not finalizing the provision that would require POs to audit and monitor their operations, but we are finalizing the provision that would require POs to identify, respond to and correct non-compliance and fraud, waste and abuse.

In section III.F.2. of this final rule, we are not finalizing the proposal to add a new § 460.62(a)(8) specifying that the governing body of the PO must have full legal authority and responsibility for adopting and implementing the compliance oversight program.

In section III J.1. of this final rule, we are revising § 460.182(b)(3) to require that the Medicaid capitation rate provides for reasonable, appropriate and attainable costs that are required under the PACE program agreement for the operation of the PO for the time period and the population covered.

V. 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. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comments 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.

On August 16, 2016 (81 FR 54692 through 54697), we solicited public comment on each of these issues for the following sections in the proposed rule that contained information collection requirements. As indicated below, we received comments pertaining to the IDT under § 460.102. Otherwise, no PRA-related comments were received and the provisions were adopted as proposed.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2016 National Occupational Employment and Wage Estimates for all salary estimates (*www.bls.gov/oes/current/oes_nat.htm*). In this regard, Table 2 presents the mean hourly wage, the cost of fringe benefits and support costs (calculated at 100 percent of salary), and the adjusted hourly wage for the occupation code, 29–9000, ''Other Healthcare Practitioners and Technical occupations,'' in the occupational category 29–0000, ''Healthcare Practitioners and Technical Occupations.'' This code was selected since it includes PO, CMS and State staff working in healthcare but who do not have specialist or technical specialist titles.

TABLE 2—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

BLS occupation title	BLS occupation code	BLS mean hourly wage ($/hr)	Fringe benefits and support costs ($/hr)	Adjusted hourly wage ($/hr)
Other Technical Occupations (hereinafter, technical staff)	29–9000	31.19	31.19	62.38

B. Proposed Information Collection Requirements (ICRs)

1. ICRs Regarding Global Change for Quality Assessment and Performance Improvement (Part 460)

This final rule replaces all references to ''quality assessment and performance improvement'' to read ''quality improvement'' in §§ 460.32(a)(9), 460.60(c), 460.62(a)(7), 460.70(b)(1)(iii), 460.120(f), 460.122(i), 460.130(a), 460.132(a) and (c)(3), 460.134(a), 460.136(a), (b), (c), (c)(1) and (c)(2) 460.138(b), and 460.172(c). The change also affects the heading for subpart H and the section headings for §§ 460.132, 460.134, and 460.136.

For each PO, we estimate a one-time burden of 1 hour at $62.38hr for technical staff to replace or amend existing written materials with the updated term. In aggregate, we estimate an annualized burden of 41.3 hours ([124 PO × 1 hour] ÷ 3) at a cost of $2576 (41.3 hr. × $62.38/hr). We are annualizing the one-time estimate since we do not anticipate any additional burden after OMB's 3-year approval period expires. The revised requirements and added burden have been submitted to OMB for approval under control number 0938–0790 (CMS–R–244). This information request is subject to renewal. The control number's current expiration date is June 30, 2020.

2. ICRs Regarding Application Requirements (§ 460.12)

While § 460.12 sets forth general application requirements for an entity seeking to become a PO, current regulations do not specify the process for an existing PO to submit an application to expand its service area and/or add a new PACE center site. In § 460.12(a), we proposed revisions to specify that this section also applies to expansion applications. This change would codify (in the CFR) the current PACE manual requirements pertaining to application submissions.

Until 2016 for initial PACE applications and 2017 for expansion applications, PACE applications were submitted in hard copy format. Applications were often hundreds of pages long, expensive to reproduce and transmit, and administratively inefficient. This rule finalizes our proposal to add the phrase ''in the form and manner specified by CMS'' under § 460.12(a) when describing the submission of a complete application to CMS. This change provides flexibility in the submission of applications, supporting documentation, and CMS notifications. With this change CMS expects that PACE applications will be submitted in a fully electronic submission process, thereby reducing the expense of submitting a hard copy application. CMS has successfully transitioned other programs to a fully electronic submission process, thereby facilitating a more organized and streamlined review.

Section 460.12(b) requires that a PO's application must be accompanied by an assurance (from the SAA of the state in which the program is located) indicating that the state considers the entity to be qualified as a PO and is willing to enter into a program agreement with the entity. This rule also finalizes our proposal under § 460.12(b)(2) to require that an expansion application include the state's assurance that the state is willing to amend the PACE program agreement to include new PACE center sites and/or expand its service area. This change codifies the current PACE manual provisions pertaining to the practice of application submissions.

Section 460.12(c)(1) requires that an entity submitting an application to become a PO or a PO submitting an application to expand its service area must describe the proposed service area in its application. As this is current practice, this action would not add any new burden to the applicants. To become a PO, the requirement for an entity to submit an application that describes the proposed service area is set out under § 460.22. The application for a PO to expand its service area also requires this information. The requirements and burden are currently approved by OMB under control number 0938–1326. Subject to renewal, the expiration date specific to this control number is December 31, 2021.

3. ICRs Regarding the Submission and Evaluation of Waiver Requests (§ 460.26)

Section 460.26 discusses the requirements to submit a waiver seeking to modify a PACE program requirement. Although current regulations require that a waiver request be submitted to the SAA for review prior to submitting to CMS, we finalized our proposal to reorganize the CFR text so it is clear that both current POs and applicants must submit a waiver request to the SAA prior to submitting their request to CMS. The reorganized CFR text also clarifies that a waiver request may be submitted with the application or as a separate document. The requirements for submitting a waiver request are being clarified and are not changing our currently approved burden estimates for POs and applicants. The preceding requirements and burden are approved by OMB under control number 0938–0790 (CMS–R–244, expires, June 30, 2020).

4. ICRs Regarding Notice of CMS Determination on Waiver Requests (§ 460.28)

Section 426.28(a) discusses the timeframes for CMS to make a determination and to send notification about the approval or denial of a waiver request. While current language requires that CMS approve or deny a waiver request within 90 days of receipt of the request, we revised the requirement so

that CMS must approve or deny a request after receiving a complete waiver request. Since CMS will request additional information from the PO if a waiver request is not complete, this change is needed since it is not possible to make an informed decision for approval or denial when important information is missing. This change will help facilitate CMS' ability to work with the PO or applicant to ensure that the request includes all necessary information. The change is not expected to change the burden on POs and applicants. The requirements and burden are approved by OMB under control number 0938–0790 (CMS–R–244, expires June 30, 2020).

5. ICRs Regarding the PACE Program Agreement (§ 460.32)

Sections 460.32 and 460.180(b) require that PACE program agreements specify the methodology used to calculate the Medicare capitation rate. For the Medicaid capitation rates, however, the PACE program agreement must specify the actual amount negotiated between the POs and the SAA (§§ 460.32(a)(12) and 460.182(b)). In this rule we are finalizing our proposal to amend § 460.32(a)(12) by requiring that the program agreement include the Medicaid capitation rates or the Medicaid payment rate methodology. This would be in addition to the current requirement to include the methodology used to calculate the Medicare capitation rate.

Medicaid capitation rates are developed and updated by the states (in negotiation with the POs) and approved by CMS. Operationally, states submit documentation to CMS to support their proposed PACE Medicaid capitation rates. CMS reviews the documentation to ensure the proposed rates are in compliance with the requirements of § 460.182 and provides the state with written approval of the rates. The Medicaid capitation rates are then communicated to the POs by the state in writing.

Since current regulations require that the PACE program agreement include the Medicaid capitation rates, this also requires that the PACE program agreement be updated to reflect the rates each time they change, which for most POs is annually. We do not believe it is always practical or efficient to include the actual Medicaid capitation rates in the PACE program agreement. In response, we finalized our proposal to amend § 460.32(a)(12) by requiring that the program agreement include the Medicaid capitation rates or the Medicaid payment rate methodology. We do not estimate any additional burden to the PO or the state as a result of this change. During the next regular rate update, the PACE program agreement may be revised to include the state's Medicaid payment rate methodology instead of the new rates. This would have been an update that would have already been required under the current requirements at § 460.32(a)(12). By removing the requirement that PACE program agreements be updated to include the Medicaid capitation rates, we estimate that each PO would save 30 minutes annually. Therefore, we estimate an aggregate annual reduction of 62 hours (124 POs x 0.5 hr) at a savings of $3,868 (62 hr x $62.38/hr).

The revised requirement and burden have been submitted to OMB for approval under control number 0938–0790 (CMS–R–244, expires June 30, 2020).

6. ICRs Regarding a Governing Body (§ 460.62)

Section 460.62 focuses on the ability of the PO's governing body to provide effective administration in an outcome-based environment. While § 460.62(a)(7) requires that a PO's governing body be able to administer a quality improvement program, this rule revises this section by requiring that the PO's governing body must be able to administer a quality improvement program as described in the general rule regarding quality improvement programs found in § 460.130.

Section 460.132 already requires that the PO implement a quality improvement plan and that the governing body must review the quality improvement plan on an annual basis. Revisions to § 460.62(a)(7) simply clarify what quality improvement program the PO's governing body must be able to administer. The burden associated with the aforementioned requirements is captured in § 460.132 which is approved by OMB under control number 0938–0790 (CMS–R–244, expires June 30, 2020).

7. ICRs Regarding the Creation of a Compliance Oversight Program (§ 460.63)

In the proposed rule we proposed to create a new section, § 460.63 that would have required all POs to implement compliance oversight programs for their organizations that was would parallel the existing compliance program infrastructure required of Part D plan sponsors. In particular, we proposed requiring that POs have compliance oversight programs for their entire organization with two compliance elements, 1) internal monitoring and auditing, and 2) prompt response, investigation and correction of non-compliance and fraud, waste and abuse.

As described in section III.F.3. of this final rule, we received several comments related to underestimating the burden on the proposed compliance oversight program. Specifically, commenters suggested that additional staff and resources would be required to implement the two proposed provisions across the PO's full operations. As a result of these comments we are not finalizing the proposal to require POs to adopt compliance oversight requirements related to internal monitoring and auditing but are finalizing a new § 460.63 which requires POs to have a compliance oversight program for responding to compliance issues, investigating potential compliance problems, and correcting non-compliance and fraud, waste and abuse.

In the proposed rule, based on our experience with the program we estimated 150 hours to create training materials and devote staff to implementing the new program. We estimated this burden based on our combined experience with compliance programs in MA and Part D as those programs, like PACE are structured so that there is a single organization responsible for the care of enrollees/participants. We then used that experience and modified it to account for POs size and staffing. We believe that given the size of most POs, a one-time burden of 150 hours would be a reasonable estimate on how long it would take to ensure new program materials were developed.

In this final rule, because we are not finalizing the requirement for POs to adopt internal monitoring and auditing we are reducing the 150 hour estimate of the one-time burden for each PO by a factor of 10. In addition, since we published the proposed rule, the number of POs has increased from 119 to 124.

For each PO, we estimate a one-time burden of 15 hours at $62.38/hr for technical staff to create written training materials and written procedures for the expansion of a PO's existing system of responding to and correcting non-compliance (that the PO previously established in its role as a Part D plan sponsor) to prospectively encompass all of its PACE operations. In aggregate, we estimate an annualized burden of 620 hours ([124 PO × 15 hour] ÷ 3) at a cost of $38,676 (620 hr × $62.38/hr). We are annualizing the one-time estimate since we do not anticipate any additional

burden after OMB's 3-year approval period expires.

To estimate the annual burden of reporting fraud and abuse, we assume each PO would take 20 hours annually. Therefore, the aggregate hourly burden is 2,480 hr (124 POs × 20 hours), at an aggregate cost of $154,702 (2,480 hr × $62.38/hr).

The revised requirements and added burden have been submitted to OMB for approval under control number 0938–0790 (CMS–R–244, expires June 30, 2020).

8. ICRs Regarding Personnel Qualifications for Staff With Direct Participant Contact (§ 460.64(a)(3))

Section 460.64(a)(3) requires that employees or contractors of the PO who have direct participant contact must have 1 year of experience working with a frail or elderly population. We amended this requirement by allowing the PO to hire employees or contractors with less than 1 year of experience working with a frail or elderly population as long as they meet all other qualification requirements under § 460.64(a) and receive appropriate training on working with a frail or elderly population upon hiring.

Section 460.71 already includes requirements regarding training of staff and competency evaluations for employees and contracted staff furnishing care directly to participants. In this regard the revisions to § 460.64(a)(3) do not have any effect on the burden that is currently approved by OMB under control number 0938–0790 (CMS–R–244, expires June 30, 2020).

9. ICRs Regarding Program Integrity (§ 460.68(a))

Section 460.68 was established to guard against potential conflicts of interest or certain other risks individuals and organizations could present to the integrity of the PACE program. The amendments to § 460.68(a)(3) enable POs to determine whether an individual's contact with participants would pose a potential risk because the individual has been convicted of criminal offenses related to physical, sexual, drug, or alcohol abuse or use, rather than entirely prohibiting the hiring of such individuals. To provide POs with more safeguards against potential hires that may pose a risk to participants, we also added language in § 460.68(a)(4) and (a)(5) similar to the requirements found in regulations governing Long Term Care facilities.

In § 460.68(a)(4), we finalized our proposal to add a new restriction that would prevent POs from employing or contracting with individuals or organizations who have been found guilty of abusing, neglecting, or mistreating individuals by a court of law or who have had a finding entered into the state nurse aide registry concerning abuse, neglect, mistreatment of residents, or misappropriation of their property. Further, in § 460.68(a)(5) we finalized our proposal to add a new restriction that would prevent POs from employing individuals or contracting with organizations or individuals who have been convicted of any of the crimes listed in section 1128(a) of the Act.

We anticipate that these changes may result in employers revising their written policies and procedures related to the hiring of individuals with criminal histories and revising their employment applications. We estimate a one-time burden of 10 hr at $62.38/hr for technical staff to make these revisions to the written policies and procedures. In aggregate, we estimate an annualized burden of 413.3 hours ([124 POs × 10 hr]/3 yr) at a cost of $25,782 (413.3 hr × $62.38/hr). We are annualizing the one-time estimate since we do not anticipate any additional burden after OMB's 3-year approval period expires. The revised requirements and added burden have been submitted to OMB for approval under control number 0938–0790 (CMS–R–244, expires June 30, 2020).

10. ICRs Regarding Marketing (§ 460.82)

Section 460.82 sets out requirements governing the marketing activities of POs. In this final rule, we are allowing the use of non-employed agents/brokers, provided they are appropriately trained, to market PACE programs. We also finalized our proposal to expand the scope of prohibited marketing practices to include additional means of marketing through unsolicited contact. In addition, we finalized our proposal to remove § 460.82(f) which requires that POs establish, implement, and maintain a documented marketing plan with measurable enrollment objectives and a system for tracking its effectiveness. We no longer believe that the documented marketing plan is necessary as we already review all marketing materials used by a PO and enrollments are already tracked by CMS. We do not believe that a marketing plan is an integral piece of the PACE program and does not provide value to the PO or to CMS. In response, we anticipate that these changes may result in POs needing to review existing policies and procedures to make sure they incorporate the changes, as well as to update any current marketing materials that may need to be changed as a result of the regulatory changes.

We estimate a one-time burden of 5 hr at $62.38/hr for technical staff to revise the written marketing policies and materials. In aggregate, we estimate an annualized burden of 206.7 hours ([124 POs × 5 hr]/3 yr) at a cost of $12,894 (206.7 hr × $62.38/hr).

At the same time, we estimate a burden reduction related to removing the requirements for the marketing plan and the tracking system. We estimate this will save each PO 10 hours annually. We estimate an aggregate reduction of 1,240 hours (124 POs × 10 hr) at a savings of $77,351 (1,240 hr × $62.38/hr).

We are annualizing the one-time estimates since we do not anticipate any additional burden after OMB's 3-year approval period expires. The revised requirements and burden have been submitted to OMB for approval under control number 0938–0790 (CMS–R–244, expires June 30, 2020).

11. ICRs Regarding the IDT (§ 460.102)

Section 460.102 currently states that primary medical care must be furnished to a participant by a PACE primary care physician. This final rule will allow primary care to be furnished by a ''primary care provider'' rather than a ''primary care physician.'' The PO must revise or develop policies and procedures for the oversight of its primary care providers.

This final rule permits a PO to have one individual fulfill two separate roles on an IDT when the individual meets applicable state licensure requirements and is qualified to fill each role and able to provide appropriate care to meet the participant's needs.

In response to public comments to proposed rule CMS–4168–P, this final rule further revises § 460.102 to delete the requirement that members of the IDT must serve primarily PACE participants.

We estimate a one-time burden of 1 hr at $62.38/hr for technical staff to update their PO's policy and procedures. In aggregate, we estimate an annualized burden of 41.3 hr ([124 POs × 1 hr]/3 yr) at a cost of $2,576 (41.3 hr × $62.38/hr). We are annualizing the one-time estimate since we do not anticipate any additional burden after OMB' 3-year approval period expires. The revised requirements and added burden have been submitted to OMB for approval under control number 0938–0790 (CMS–R–244, expires June 30, 2020).

12. ICRs Regarding Participant Assessment (§ 460.104)

Section 460.104 sets forth the requirements for PACE participant assessments. The information obtained through the assessment is the basis for the plan of care developed by the IDT. If the IDT determines from its assessment that certain services do not need to be included in the participant's care plan, revisions to § 460.104(b) would require that the IDT must document in the care plan the reasons why such services are not needed and are not being included in the plan.

As both the development of and updates to the care plan are a typical responsibility for the IDT we believe that any burden associated with this would be incurred by persons in their normal course of business. We believe that the burden associated with the development of and updates to the care plan are exempt from the PRA in accordance with 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities and is a usual and customary business practice.

Currently, § 460.104(c) sets forth the requirements for periodic reassessments, including semiannual and annual reassessments. In this rule we are finalizing our proposal to remove the requirement in § 460.104(c)(2) requiring annual reassessments by the physical therapist, occupational therapist, dietician, and home care coordinator. In addition to the periodic reassessments, § 460.104(d) sets forth the requirements for unscheduled reassessments. In this final rule, we are revising § 460.104(d)(2) to specify that the appropriate members of the IDT may use remote technologies to conduct unscheduled reassessments when a participant or his or her caregiver or designated representative makes a request to initiate, eliminate or continue a particular service, and the IDT determines that the use of remote technology is appropriate and the service request will likely be deemed necessary to improve or maintain the participant's overall health status and the participant or his or her designated representative agrees to the use of remote technology.

While these requirements involve a collection of information, we believe that the burden associated with these requirements is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2). We believe that the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities and in the absence of federal regulation.

13. ICRs Regarding Plan of Care (§ 460.106)

Section 460.106(a) requires that a participant's plan of care be developed by the IDT promptly. This final rule amends this requirement by specifying that the IDT must develop the plan of care within 30 days of the participant's date of enrollment. In § 460.106(b), we finalized the following three new requirements pertaining to the content of the plan of care: (1) The plan must utilize the most appropriate interventions for each of the participant's care needs that advances the participant toward the measurable goals and desired outcomes; (2) the plan must identify each intervention and how it will be implemented; and (3) the plan must identify how each intervention will be evaluated to determine progress in reaching specified goals and desired outcomes.

We believe these changes provide clarification regarding the current requirements in § 460.106 on how to develop and implement a plan of care, and document any changes made to the plan of care in the participant's medical record. We expect POs to keep up-to-date with current practice standards related to plans of care and believe that most POs already implement these requirements. As we stated in the 1999 IFC (64 FR 66276), the development of the plan of care is subject to the PRA; however, we stated that the burden associated with this revision is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities and in the absence of federal regulation.

14. ICRs Regarding Explanation of Rights (§ 460.116)

Section 460.116 sets forth requirements for POs with respect to explanation of rights, such as having written policies and procedures on these rights, explaining the rights, and displaying the rights. Section 460.116(c)(1) provides that the PO must write the participant rights in English and in any other principal languages of the community. In this rule we are finalizing our proposal to require that if a state has not established a standard for making the principal language determination, a principal language of the community is any language spoken regularly at home by at least 5 percent of the individuals in the PO's service area.

We anticipate that these changes may result in technical staff revising documents. We estimate a one-time burden of 5 hr at $62.38/hr for technical staff to revise the written material about participant rights. In aggregate, we estimate an annualized burden of 206.7 hours ([124 POs × 5 hr]/3 yr) at a cost of $12,894 (206.7/hr × $62.38/hr). Section 460.116(c)(2) states that the PO must display the participant rights in a prominent place in the PACE center. In this rule we are finalizing our proposal to add the word ''PACE'' before the words ''participant rights'' to specify that participant rights specific to PACE must be displayed.

We anticipate that these changes may result in technical staff revising documents. Since the only change is the addition of the word ''PACE'' and redisplay of notices, we estimate a one-time burden of 0.5 hr at $62.38/hr for technical staff to revise the notices. In aggregate, we estimate an annualized burden of 20.7 hours ([124 POs × 0.5 hr]/3 yr) at a cost of $1,291 (20.7 hr × $62.38/hr).

We are annualizing the one-time estimates since we do not anticipate any additional burden after OMB's 3-year approval period expires. The revised requirements and added burden have been submitted to OMB for approval under control number 0938–0790 (CMS–R–244, expires June 30, 2020).

15. ICRs Regarding Quality Improvement General Rule (§ 460.130)

Section 460.130 requires a PO to develop, implement, maintain, and evaluate a quality assessment and performance improvement program which reflects the full range of their services. Section 460.140 refers to additional quality assessment activities related to reporting requirements. In this rule we are finalizing our proposal to combine § 460.140 with § 460.130 in an effort to combine all the general rules for quality improvement under the first section in subpart H, and would entirely remove § 460.140. This regulatory reorganization has no impact on any requirements or burden estimates.

16. ICRs Regarding Quality Performance Reporting (§ 460.132)

Section 460.132 sets forth requirements with respect to a Quality Assessment and Performance Improvement (QAPI) plan. In this rule we are finalizing our proposal to revise § 460.132(a) and (c)(3) by referring to a quality improvement (QI) plan. Revisions would also require that POs have a written quality improvement

plan that is collaborative and interdisciplinary in nature. Because POs are already required to have a written QAPI plan, we anticipate added burden to update the plan by making it more collaborative and interdisciplinary in nature.

We estimate a one-time burden of 1 hour at $62.38/hr to update material. In aggregate, we estimate an annualized burden of 41.3 hours ([124 POs × 1 hr]/3 yr) at a cost of $2,576 (41.3 hr × $62.38/hr) to update QI plans. We are annualizing the one-time estimate since we do not anticipate any additional burden after OMB's 3-year approval period expires. The revised requirements and added burden have been submitted to OMB for approval under control number 0938–0790 (CMS–R–244, expires June 30, 2020).

17. ICRs Regarding the Enrollment Process (§ 460.152)

Section 460.152(b)(4) states that the PO must notify CMS and the SAA if a prospective participant is denied enrollment. In this rule we are finalizing our proposal to add the phrase, ''in the form and manner specified by CMS'' and to codify current practice in which such notifications are submitted to CMS and SAA electronically, noting that this change would not revise any requirements or burden estimates. The requirements and burden are approved by OMB under control number 0938–0790 (CMS–R–244). Subject to renewal, the control number's current expiration date is June 30, 2020.

18. ICRs Regarding the Enrollment Agreement (§ 460.154)

Section 460.154 specifies the general content requirements for the enrollment agreement. Specifically, § 460.154(i) states that the enrollment agreement must provide notification that enrollment in PACE results in disenrollment from any other Medicare or Medicaid prepayment plan or optional benefit. We require additional enrollment agreement language stating that if a Medicaid-only or private pay PACE participant becomes eligible for Medicare after enrollment in PACE, he or she will be disenrolled from PACE if he or she elects to obtain Medicare coverage other than from his or her PO.

We estimate a one-time burden of 1 hour at $62.38/hr to update enrollment materials. In aggregate, we estimate an annualized burden of 41.3 hr ([124 POs × 1 hr]/3 yr) at a cost of $2,576 (41.3 hr × $62.38/hr). We are annualizing the one-time estimate since we do not anticipate any additional burden after OMB's 3-year approval period expires. The revised requirements and added burden have been submitted to OMB for approval under control number 0938–0790 (CMS–R–244). Subject to renewal, the control number's current expiration date is June 30, 2020.

19. ICRs Regarding the Enrollment Procedures (§ 460.156)

While § 460.156(a) currently requires that POs provide participants with, among other items, stickers for the participant's Medicare and Medicaid cards, we finalized our proposal to revise this requirement such that POs would no longer be required to provide participants with stickers for their Medicare and Medicaid cards. Instead, POs would be required to include the PO's phone number on the participant's PO membership card.

Since we would no longer require that POs provide stickers for participants' Medicare and Medicaid cards, we estimate an annual decrease of 1 minute for each organization. The aggregate annual reduction is 2.1 hours (124 POs × 1 minute/response) at a savings of $131 (2.1 hr × $62.38/hr). The revised requirements and burden have been submitted to OMB for approval under control number 0938–0790 (CMS–R–244). Subject to renewal, the control number's current expiration date is June 30, 2020.

Additionally, we believe that the burden associated with including the phone number of the PO on the PACE membership card is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities and is a customary business practice that would occur in the absence of federal regulation.

20. ICRs Regarding Involuntary Disenrollment (§ 460.164)

Section 460.164 specifies the conditions under which a PACE participant can be involuntarily disenrolled from a PACE program, including when a participant engages in disruptive or threatening behavior. We have approved several waivers which allow a PO to involuntarily disenroll a participant in situations where the participant's caregiver engages in disruptive or threatening behavior. In this rule we are finalizing our proposal to permit involuntary disenrollment in situations where the participant's caregiver engages in disruptive or threatening behavior, which is defined as exhibiting behavior that jeopardizes the participant's health or safety, or the safety of the caregiver or others.

The revision would obviate the need for such waivers, thereby reducing the burden on POs, states, and CMS. Since we continue to estimate that fewer than 10 POs would submit this type of waiver request each year, we believe the requirement is not subject to the PRA in accordance with 5 CFR 1320.3(c)(4).

21. ICRs Regarding the Disclosure of Review Results (§ 460.196)

Section 460.196 requires that POs make their review results available in a location that is readily accessible to their participants. In this rule we are finalizing our proposal to amend § 460.196(d) to ensure that POs make review results available for examination not just by PACE participants, but by those individuals who may be making decisions about PACE participants' care, such as family members, caregivers and authorized representatives, because we believe they should be fully aware of the PO's performance and level of compliance with statutory and regulatory requirements.

We anticipate that these changes may result in technical staff redisplaying documents. We estimate a one-time burden of 0.5 hr at $62.38/hr for technical staff to redisplay the review results. In aggregate, we estimate an annualized burden of 20.7 hours ([124 POs × 0.5 hr]/3 yr) at a cost of $1,291 (20.7 hr × $62.38/hr). We are annualizing the one-time estimate since we do not anticipate any additional burden after OMB' 3-year approval period expires. The revised requirements and added burden have been submitted to OMB for approval under control number 0938–0790 (CMS–R–244, expires June 30, 2020).

22. ICRs Regarding the Maintenance of Records and Reporting of Data (§ 460.200)

In accordance with § 460.200(f)(1), POs must retain records for the longest of the following periods: the period of time specified in state law; 6 years from the last entry date; or for medical records of disenrolled participants, 6 years after the date of disenrollment. In this rule we are finalizing our proposal to change this requirement from 6 to 10 years.

We believe that the burden to store records for 6 years is sufficient to cover the storage for 4 more years, especially as data are increasingly likely to be stored electronically. As for the storage of electronic records, a server is not needed since a terabyte hard drive costs under $200 and can store a terabyte of data securely. Furthermore, most servers have additional capacity which could be used before more expenses are needed.

Thus, the expense to go from 6 years to 10 years is minimal so we are not itemizing this burden. The requirements and burden for storing records for 6 years are currently approved by OMB under control number 0938–0790 (CMS–R–244, expires June 30, 2020). The revised requirements have been submitted to OMB under this control number for approval.

C. Summary of Annual Burden Estimates for Requirements

TABLE 3—INFORMATION COLLECTION REQUIREMENTS AND BURDEN *

Section(s) in title 42 of the CFR	OMB control number (expires June 30, 2020)	Respondents	Responses (per respondent)	Burden per response (hr)	Total time (hr)	Labor cost per hour ($/hr)	Total cost (annual in dollars)
part 460 (global term change)	0938–0790	124	1	1	** 41.3	62.38	** 2,578
§ 460.32 (program agreement)	0938–0790	124	1	-0.5	−62	62.38	−3,868
§ 460.63 (update policies and procedures)	0938–0790	124	1	15	620.0	62.38	38,676
§ 460.63 (annual report of fraud and abuse)	0938–0790	124	1	20	2,480.0	62.38	154,702
§ 460.68(a) (program integrity for PACE)	0938–0790	124	1	10	413.3	62.38	25,784
§ 460.82 (revise policies and written materials)	0938–0790	124	1	5	206.7	62.38	12,892
§ 460.82 (remove requirements)	0938–0790	124	1	−10	−1240	62.38	−77,351
§ 460.102 (update policies and procedures)	0938–0790	124	1	1	41.3	62.38	2,578
§ 460.116 (revise explanations of rights)	0938–0790	124	1	5	206.7	62.38	12,892
§ 460.116 (redisplay 'participant rights' as 'PACE participant rights')	0938–0790	124	1	0.5	20.7	62.38	1,289
§ 460.132 (update QI plan)	0938–0790	124	1	1	41.3	62.38	2,578
§ 460.154 (revise enrollment agreement)	0938–0790	124	1	1	41.3	62.38	2,578
§ 460.156 (removing sticker requirement)	0938–0790	124	1	−0.017	−2.1	62.38	−131
§ 460.196 (disclosure of review results)	0938–0790	124	1	0.5	20.7	62.38	1,289
TOTAL		124	1	varies	2,829.2	Varies	176,486

* The $154,702 burden for § 460.63 is an annual burden. All other cost burdens are first year burdens which have been annualized by dividing by 3 since we do not anticipate any further burden. All items with savings are annual for each of the 3 years.

** To clarify rounding procedures: 2,578 = 124 total respondents × ⅓ (annualized for 3 years) × 62.38. However, the 124/3 is displayed as 41.3 not 41.3333.

D. Submission of PRA-Related Comments

We have submitted a copy of this final rule to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by OMB.

We invite public comments on these information collection requirements. If you wish to comment, please identify the rule (CMS–4168–F) the ICR's CFR citation, CMS ID number, and OMB control number. Comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, *Fax:* (202) 395–5806 *OR, Email: OIRA_submission@omb.eop.gov.*

To obtain copies of a supporting statement and any related forms for the collection(s) summarized in this rule, you may make your request using one of following:

1. Access CMS' website at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

PRA-related comments are due July 3, 2019.

VI. Regulatory Impact Statement

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year).

To analyze the impact of this rule we reviewed its 45 provisions. We determined that 20 of the provisions have no cost or savings so we are not discussing them in this statement. Twenty two other provisions are scored in the information collection requirements section with aggregate annualized burden (for the first 3 years) of $176,486 ($257,836 in costs minus $81,350 in savings). One of those 22 provisions, (the compliance oversight provision), has effects outside of the scope of the PRA, so the additional impacts of it, and the remaining three provisions are assessed in this regulatory impact statement.

The provision discussed in section III.K.1. of this final rule, the modification of § 460.182 regarding Medicaid payment, has no savings or cost; the provision discussed in section III.L.1. of this final rule, the modification of § 460.190 regarding monitoring, has a savings of $1,523,253 to POs and a savings of $2,638,144 to the government without any transfer to POs; the provision discussed at III.G.4. of this final rule, the modification of § 460.104(d)(2) to allow use of remote technologies for certain participant assessments has a qualitative savings which is not further quantified. It follows that this final rule has a net savings of 4 million arising primarily from the monitoring provision. These estimates are summarized in detail in Table 4. We discuss these four provisions in more detail below.

TABLE 4—IMPACT [1] [2] OF FINAL RULE BY PROVISION AND YEAR

Provision name	Regulatory citation	Section of final rule	1st year savings	2nd and later year savings
Medicaid Payment	§ 460.182	III.K.1	$0	$0
Monitoring	§ 460.190	III.L.1	[3] 4,161,397	[3] 4,161,397
Participant Assessment	§ 460.104(d)(2)	III.G.4	0	0
Various [4]	Various	V	(382,754)	(73,352)
Total			3,778,643	4,088,045

Notes:

[1] Positive numbers indicate savings; negative numbers indicate cost.

[2] Although the Participant Assessment provision (Section III.G.4, § 460.104(d)(2)) is not scored quantitatively, it is a savings. The Medicaid provision is neither a savings nor cost. The additional flexibility for the IDT provision has neither cost nor savings to the government due to the fact that most POs are currently exercising these flexibilities through PACE waivers.

[3] The government saves $2,638,144 and the POs save $1,523,253.

[4] The numbers in this row are derived from the summary Table 3 in the Collection of Information section as follows: The first year cost is 382,754 and is the sum of three items: (i) The aggregate of all items saved is $81,350, (ii) The annual cost of reporting fraud and abuse is $154,702, (iii) the aggregate of all items with cost minus the $154,702 when multiplied by 3 is 309,402 (the numbers in Table 3 are divided by 3 to create an annualized cost and hence have to be multiplied by 3). The 2nd and later year costs are $73,352, the difference of $81,350 (the aggregate of all items with savings) and the $154,702 annual cost of reporting fraud and abuse.

A. Medicaid Payment (§ 460.182 (Discussed in Section III.K.1. of This Final Rule))

The provision aims to ensure that the Medicaid rate paid under the PACE program agreement is not only less than what would otherwise have been paid outside of PACE for a comparable population, but is also sufficient for the population served under the PACE program, which we believed means not lower than an amount that would be reasonable and appropriate to enable the PO to cover the anticipated service utilization of the frail elderly participants enrolled in the program and adequate to meet PACE program requirements. We will continue to review and approve Medicaid capitation rates under PACE. Therefore, we do not believe this provision will affect spending.

B. Participant Assessment (§ 460.104(d) Discussed in Section III.G.4 of This Final Rule)

This provision reduces the required IDT members at a ''change in participant status'' reassessment under § 460.104(d)(1) from 8 to 3 members and allows use of remote technology to conduct reassessments for certain participant service requests under § 460.104(d)(2). We expect the reduction of required IDT members from eight to three will result in savings by reducing labor costs. Similarly, we expect the use of remote technology for reassessments related to service delivery requests will result in savings from reduced travel costs for PO staff and PACE participants.

We are scoring this as a qualitative savings and not further quantifying it. The primary reasons for not quantifying it further are due to our inability to assess the number of these participant service requests and the typical travel time that would have been required for such reassessments. Furthermore, removing a travel requirement for requests might result in an increase in requests and this effect is difficult to quantify.

C. Monitoring (§ 460.190 (Discussed in Section III.L.1. of This Final Rule))

This provision would result in savings to both the POs and the government without any transfers to the POs. We estimate separately the savings for POs and the government below.

To estimate the savings from the monitoring provision we use the following assumptions, based on our experience with audits. Since publishing the proposed rule, we have implemented a new PACE audit protocol. Having used that new protocol for two years, we now have a better understanding of the costs of audits to both PO's and the government. We are updating our analysis to reflect our current projections, which result in significantly increased estimated savings for both POs and the government.

Under the provision we are finalizing, we estimate that we will perform 35 audits per year, 20 during PO trial periods and 15 post trial period (routine) audits. If we did not finalize this provision, we estimate that we would perform 72 audits per year, 34 during PO trial periods, and 38 post trial period (routine) audits.

In the proposed rule, we made the following assumptions in estimating costs of an audit for a PO. Mean hourly wages have been updated to reflect current estimates. The assumptions are summarized in Table 5.

- *Personnel:* We estimated:

++ 2 Medical and Health Service Managers, occupational code 11–9111 on the Bureau of Labor Statistics (BLS) website accessible at *www.bls.gov/oes/current/oes_nat.htm,* with an average hourly wage of $53.69

++ 1 Secretary and Administrative assistant, code 43–6010, with an average hourly wage of $19.74.

However, in the time since the proposed rule was published, CMS has implemented and operated a new PACE audit protocol which has allowed us to better estimate the costs of audits on a PO. We now estimate the following for personnel:

TABLE 5—NATIONAL OCCUPATIONAL MEAN HOURLY WAGE AND ADJUSTED HOURLY WAGE

Occupation title	Occupation code	Mean hourly wage ($/hr)
Nurse Manager	11–9111	53.69
Executive Assistant	43–6011	28.56
Medical Records and Health Information Technician	29–2071	20.59
Compliance Officer	13–1041	34.39

Additionally, in the proposed rule we estimated 80 hours uniformly per person; 40 hours the week before the audit and 40 hours the week of the audit. Based on updated information, we now estimate that audits will take approximately 150 hours per person for POs to complete. This estimate includes all of the pre-audit work, including (i) compiling and (ii) submitting audit documentation; (iii) 2 weeks of audit fieldwork; the post-audit work of (iv) collecting and (v) submitting impact analyses, (vi) reviewing and (vii) commenting on the draft audit report, and (viii) submitting and (ix) implementing corrective action plans for conditions of non-compliance.

• *Fringe benefits:* We estimate 100 percent (of hourly wage) for fringe benefits and overhead.

Based on these assumptions, we can compute the difference between 72 and 35 audits per year. In the proposed rule, we estimated that POs would save approximately $737,336.00. However, based on the new assumptions, and as a result of more accurate estimates, we now estimate that savings per year to POs would be $1,523,253. The calculations are exhibited in Table 6.

TABLE 6—PO SAVINGS FROM FINALIZING THE MONITORING PROVISION

Occupational title	Code	Wage/hr	Fringe benefit factor	Number staff required	Hours per audit	Number of audits per year if provision is not finalized	Number of audits per year if provision finalized
Nurse Manager	11–9111	$53.69	2	1	150	72	35
Executive Assistant	43–6011	28.56	2	1	150	72	35
Medical Records and Health Information Technician	29–2071	20.59	2	1	150	72	35
Compliance Officer	13–1041	34.39	2	1	150	72	35
Summary descriptions					Cost per audit	Aggregate cost if not finalized	Aggregated cost if finalized
Summary dollar amounts	.....	.....	.....	.....	$41,169	$2,964,168	$1,440,915
Savings (Not finalized minus finalized)	.....	.....	.....	.....	.....	.....	1,523,253

In the proposed rule we used the following assumptions to estimate the cost of an audit for CMS.

• 2.5 FTE (Between 2 and 3 per audit). This number is based on CMS experience across different geographic regions some of which use 2 FTE and some of which use 3 FTE.

• *Hours spent:*

++ 220 hours at the GS–13 level with an hourly average wage of $46.46

++ 40 hours at the GS–15 level with an hourly average wage of $64.59

Based on our experiences auditing POs since publishing this proposed rule, we are now using the revised assumptions:

• 3 FTEs to conduct each audit and 1 FTE for audit oversight and 1 FTE to conduct audit close out activities.

• *Hours spent:*

++ 220 hours at the GS–13 level with an hourly average wage of $46.46 (includes 3 FTEs for 200 hours each and 1 FTE for 20 hours)

++ 60 hours at the GS–15 level with an hourly average wage of $64.59

In the proposed rule, we estimated that travel cost approximately $1,395 per audit. However, since this proposed rule was published, we now estimate that travel costs approximately $5,940 per audit.

Finally, we continue to have the following additional assumptions related to government costs.

• *Fringe Benefits:* We estimate 100 percent (of hourly wage) for fringe benefits

Based on these assumptions, we can compute the difference between 72 and 35 audits per year. In the proposed rule, we estimated that the savings to CMS was $1,029,454.70 per year. Based on the revised assumptions, we now estimate the savings to the government to be $2,638,144. The calculations are exhibited in Table 7.

TABLE 7—GOVERNMENT SAVINGS FROM FINALIZING THE MONITORING PROVISION

Occupational title	Code	Mean hourly wage	Fringe benefit	Number staff needed	Hours per audit	Number of audits per year if provision is not finalized	Number of audits per year if provision finalized
CMS Staff Employee	GS 13–1	$46.46	2	3	200	72	35
CMS Staff Employee	GS 13–1	46.46	2	1	20	72	35
CMS Manager	GS 15–1	64.59	2	1	60	72	35
Cost of Travel	.....	1,980.00	1	3	1	72	35
Summary descriptions					Cost per audit	Aggregate cost if not finalized	Aggregated cost if finalized
Summary dollar amounts	.....	.....	.....	.....	$71,301	$5,133,686	$2,495,542
Savings (Not finalized minus finalized)	.....	.....	.....	.....	.....	.....	2,638,144

D. The Compliance Oversight Program (§ 460.63 (Discussed in Section III.F.3. of This Proposed Rule))

In the proposed rule, we pointed out that current regulations do not require POs to implement compliance programs similar to those required in the regulations governing the MA and Part D programs, and we proposed to adopt certain compliance oversight requirements through the addition of § 460.63.

Currently, POs participating in the Part D program are required to have a compliance plan with measures that prevent, detect, and correct fraud, waste and abuse as specified in § 423.504(b)(4)(vi) governing the Part D program. We proposed adopting PACE program requirements that would result in POs expanding their already existing Part D compliance programs under the Part D program to ensure compliance oversight for the totality of the PO's operations. Specifically, we proposed to require all POs to establish and implement compliance efforts geared toward: (1) Routine monitoring and identification of compliance risks and (2) promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence; and ensuring ongoing compliance with CMS requirements.

In the proposed rule, we proposed a burden associated with the requirements under § 460.63 which would be the time and effort for each of the 119 POs to develop, adopt, and implement procedures for conducting internal auditing and monitoring to ensure compliance with CMS program requirements. POs would also be required to develop measures to detect, correct, and prevent fraud, waste, and abuse. POs will be required to devote technical staff to developing and implementing these procedures.

In the proposed rule, we estimated a one-time burden of 150 hours at $59.44 per hour for technical staff to develop the aforementioned procedures and measures at an annualized cost of $353,668 (119 POs × 59.44/hour × 150/3) for each of the first 3 years. We estimated this burden based on our combined experience with compliance programs in MA and Part D. Since we proposed to utilize two of the same compliance requirements in PACE as are used in MA and Part D, we believe this comparison will be accurate. We then used that experience and modified it to account for POs size and staffing. We believe that given the size of most POs, a one-time burden of 150 hours would be a reasonable estimate on how long it would take to ensure new program materials and measures were developed.

Additionally, once the program has been developed and is running, we indicated in our proposal that the PO would have to spend some time going forward monitoring their own compliance, and reporting and responding to any suspected fraud, waste and abuse. Therefore, in the proposed rule, we estimated a burden of 200 hours at $59.44 per hour for technical staff to complete these activities including, when warranted, revision of the aforementioned program materials and monitoring measures. Our estimate also included the routine monitoring and identification of compliance risks as identified in the course of self-evaluations and audits. We estimated total aggregate annual cost at $1,414,672 (119 organizations × 200 hour × $59.44 per hour). Again, given the size of POs and the limited number of participants, we believed the burden to be small, and we believed that 200 hours would cover the ongoing responsibilities of each PO. This includes PO monitoring of its own compliance; corrective action as a result of that monitoring; and updating PO monitoring measures and procedures.

We solicited comments from POs regarding this burden estimate in the proposed rule. The following is a summary of the public comments we received on the ''Compliance Oversight Program'' proposed burden estimate and our response to those comments.

Comment: Many commenters suggested that we underestimated the burden of implementing a compliance oversight program in PACE. These commenters suggested more staff would be needed, and the cost and hours to both implement and maintain a compliance oversight program were underestimated. One commenter suggested we use our burden estimates for the monitoring proposal in Subpart K in order to estimate the burden of POs implementing an internal monitoring and auditing program as a part of the compliance oversight program, since the same staff would likely be used. One commenter mentioned that the time involved in conducting ongoing internal monitoring would be similar to the time POs currently spend when undergoing a CMS audit. Another commenter mentioned that there would be a large increase in manual data collection which needed to be included in the burden.

Response: Based on comments received, and because we have a strong policy interest in not creating undue burden, we have reviewed our proposed provision and the proposed burden associated with it. We believe that the majority of the burden associated with our initial proposal is due to the first element of our proposal which would have required POs to adopt internal monitoring and auditing that would cover all PACE operations. Because POs are currently required to have a compliance program as Part D plan sponsors, we estimated the cost of new PACE requirements would be to update materials and expand efforts currently in place under Part D to implement these new PACE provisions and ensure that the full PACE operations were being affirmatively reviewed and that compliance concerns identified anywhere in the PO's operation were being promptly addressed. Although we did not separately analyze the cost of each of these two elements in our first proposal, the majority of burden was associated with the development and implementation of the internal monitoring and auditing element. We are not finalizing that element at this time in order to further evaluate the anticipated burden. We are finalizing the compliance oversight requirements which require promptly responding to non-compliance and fraud, waste and abuse. Because we are not expanding the scope of what an organization is required to monitor and because we believe POs are currently addressing compliance concerns in their organizations as they arise outside of Part D, we anticipate only a minimal burden with this element. Therefore, we revised our burden estimates and decreased the hours to implement this revised provision by a factor of 10. The number of hours would therefore be reduced from 150 hours to 15 hours for one staff member. Additionally, we decreased the estimate of how many hours an organization will spend following the implementation of this provision from 200 to 20 hours. We decreased these numbers because we are not finalizing the element that would have required POs to expand their internal monitoring and auditing efforts, and we are only finalizing the provision that would require an organization to have a system for responding to, investigating and correcting non-compliance. Since there will be no increased data collection, we believe this reduced burden accurately reflects the revised provision.

As discussed above, and as a result of these comments, we have decided not to

finalize the first proposed element related to internal monitoring and auditing, and finalize only the second element of the proposed compliance oversight program, related to responding to, correcting and reporting non-compliance and fraud, waste and abuse.

As in the proposed rule we make separate estimates for the initial year and for subsequent years. Additionally, since the proposed rule was published the number of POs increased from 119 to 124. Because we are not adopting the element of the proposal that would have required POs to establish internal monitoring and auditing the estimates of 150 and 200 hours use in the proposed rule are reduced by a factor of 10. Table 8 exhibits the estimates under the proposed and final rule. As we are finalizing, we estimate an initial year burden of $116,026.80 (or $38,675.6 per year for 3 years) and a subsequent burden of $154,702.40 for later years.

TABLE 8—IMPACT OF THE COMPLIANCE PROVISION (PROPOSED AND FINAL RULE)

Item	Proposed rule initial year	Final rule initial year	Proposed rule subsequent years	Final rule subsequent years
Number of POs	119	124	119	124
Wage estimates per hour	59.44	62.38	59.44	62.38
Hours needed to develop and implement training	150	15	200	20
Total burden [1]	$1,061,004	$116,027	$1,414,672	$154,702

Notes:
[1] Total burden is the product of the previous three rows: Number of POs * Wages Estimates Per Hour * Hours needed to develop and implement training.

Based on the above analysis, we have determined that this final rule does not reach the economic threshold, and therefore, it is neither an ''economically significant rule'' under E.O. 12866, nor a ''major rule'' under the Congressional Review Act.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has significant impact on a substantial number of entities. However, as shown in Table 4, this final rule has a net impact of savings, not cost, and consequently, we are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that our changes to this regulation would not have a significant economic impact, nor net additional costs requiring possible regulatory relief, on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. As previously explained, this rule will allow for increased staffing flexibility among POs; therefore, we are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this final rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately $154 million This rule will not mandate any requirements for state, local, or tribal governments nor would it result in expenditures by the private sector meeting that threshold in any 1 year.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Under Executive Order 13132, this final rule will not significantly affect the states beyond what is required and provided for under sections 1894 and 1934 of the Act. It follows the intent and letter of the law and does not usurp state authority beyond what the Act requires. This rule describes the processes that must be undertaken by CMS, the states, and POs in order to implement and administer the PACE program.

As noted previously, sections 1894 and 1934 of the Act describe a cooperative relationship between the Secretary and the states in the development, implementation, and administration of the PACE program. The following are some examples of areas in which we collaborated with states to establish policy and procedures for PACE, with references to the relevant sections of the Act:

(1) Establishing procedures for entering into, extending, and terminating PACE program agreements—sections 1894(e)(1)(A) and 1934(e)(1)(A) of the Act;

(2) Establishing procedures for excluding service areas already covered under other PACE program agreements in order to avoid unnecessary duplication of services and impairing the financial and service viability of existing programs—sections 1894(e)(2)(B) and 1934(e)(2)(B) of the Act;

(3) Establishing procedures for POs to make available PACE program data—sections 1894(e)(3)(A)(i)(III) and 1934(e)(2)(A)(i)(III) of the Act;

(4) In conjunction with the PO, developing and implementing health status and quality of life outcome measures for PACE participants—sections 1894(e)(3)(B) and 1934 (e)(3)(B) of the Act;

(5) Conducting comprehensive annual reviews of POs during the trial period—sections 1894(e)(4)(A) and 1934(e)(4)(A) of the Act;

(6) Establishing the frequency of ongoing monitoring—sections 1894(e)(4)(B) and 1934(e)(4)(B) of the Act;

(7) Establishing a mechanism for exercising enforcement authority—sections 1894(e)(6)(A) and 1934(e)(6)(A) of the Act.

For this reason, prior to publishing the 2006 final rule, we obtained state input in the early stages of policy development through conference calls with state Medicaid agency representatives. The statute requires that states designate the agency of the state responsible for the administration of the

PACE program. Although the state may designate the state Medicaid agency to administer the PACE program, another agency may be named. The eight agencies that volunteered to participate in these discussions represented a balanced view of states; some with PACE demonstration site experience and some who were not yet involved with PACE, but were interested in providing input to establish a new long term care optional benefit. The calls were very productive in understanding the variety of state concerns inherent in implementing a new program. In addition, in order to formulate processes to operationalize the PACE program, we have maintained ties with state representatives through monthly conference calls to obtain information on a variety of topics including the applications review and approval process, data collection needs, and enrollment/disenrollment issues. We are committed to continuing this dialogue with states to ensure this cooperative atmosphere continues as we administer the PACE program.

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017 and requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' OMB's interim guidance, issued on April 5, 2017, *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2017/M-17-21-OMB.pdf,* explains that ''E.O. 13771 deregulatory actions are not limited to those defined as significant under E.O. 12866 or OMB's Final Bulletin on Good Guidance Practices.'' Accordingly, this final rule is considered an E.O. 13771 deregulatory action. We estimate that this rule generates $3.3 million in annualized cost savings, discounted at 7 percent relative to year 2016, over a perpetual time horizon.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities. Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 460

Aged, Health care, Health records, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 1. The authority citation for part 423 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

§ 423.4 [Amended]

■ 2. Section 423.4 is amended in paragraph (4) of the definition of ''Service area (Service area does not include facilities in which individuals are incarcerated.)'' by removing the reference ''§ 460.22 of this chapter'' and adding in its place the reference ''§ 460.12(c) of this chapter''.

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

■ 3. The authority citation for part 460 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1395, 1395eee(f), and 1396u–4(f).

■ 4. Section 460.3 is added to read as follows:

§ 460.3 Part D program requirements.

PACE organizations offering qualified prescription drug coverage and meeting the definition of a Part D plan sponsor, as defined in § 423.4 of this chapter, must abide by all applicable Part D program requirements in part 423 of this chapter.

■ 5. Section 460.10 is revised to read as follows:

§ 460.10 Purpose.

(a) *Applications.* This subpart sets forth the application procedures for the following:

(1) An entity that seeks approval from CMS as a PACE organization.

(2) A PACE organization that seeks to expand its service area or to add a new PACE center.

(3) A PACE organization that seeks to expand its service area and to add a new PACE center.

(b) *Waiver.* This subpart sets forth the process by which a PACE organization may request waiver of certain regulatory requirements. The purpose of the waivers is to provide for reasonable flexibility in adapting the PACE model to the needs of particular organizations (such as those in rural areas).

■ 6. Section 460.12 is revised to read as follows:

§ 460.12 Application requirements.

(a) *Submission of application.* An individual authorized to act for an entity that seeks to become a PACE organization or a PACE organization that seeks to expand its service area and/or add a PACE center site must submit to CMS a complete application in the form and manner specified by CMS that describes how the entity or PACE organization meets all requirements in this part.

(b) *State assurance.* (1) An entity's application to become a PACE organization must include an assurance from the State administering agency of the State in which the program is located indicating that the State considers the entity to be qualified to be a PACE organization and is willing to enter into a PACE program agreement with the entity.

(2) A PACE organization's application to expand its service area and/or add a PACE center site must include an assurance from the State administering agency of the State in which the program is located indicating that the State is willing to amend the PACE program agreement to include the new site and/or expand the PACE organization's service area.

(c) *Service area designation.* (1) An entity submitting an application to become a PACE organization or a PACE organization submitting an application seeking to expand its service area must describe the proposed service area in its application.

(2) CMS, in consultation with the State administering agency, may exclude from designation an area that is already covered under another PACE program agreement to avoid unnecessary duplication of services and avoid impairing the financial and service viability of an existing program.

(d) *Service area and/or PACE center site expansion.* CMS and the State administering agency will only approve a service area expansion or PACE center site expansion after the PACE organization has successfully completed its first trial period audit and, if applicable, has implemented an acceptable corrective action plan.

■ 7. Section 460.18 is amended by—

■ a. Revising the introductory text;

■ b. Revising paragraph (b); and

■ c. Removing paragraph (c).

The revisions read as follows:

§ 460.18 CMS evaluation of applications.

CMS evaluates an application on the basis of the following information:

* * * * *

(b) Information obtained by CMS or the State administering agency through on-site visits or any other means.

■ 8. Section 460.20 is amended by—

■ a. Revising paragraph (a) introductory text;

■ b. Removing paragraph (a)(3);

■ c. Redesignating paragraphs (b) through (d) as paragraphs (c) through (e);

■ d. Adding a new paragraph (b); and

■ e. Revising newly redesignated paragraphs (c) through (e).

The revisions and addition read as follows:

§ 460.20 Notice of CMS determination.

(a) *Time limit for notification of determination.* Within 90 days, or 45 days for applications set forth in § 460.10(a)(2), after an entity submits a complete application to CMS, CMS takes one of the following actions in the form and manner specified by CMS:

* * * * *

(b) *Complete application.* An application is only considered complete when CMS receives all information necessary to make a determination regarding approval or denial.

(c) *Additional information requested.* If CMS determines that an application is not complete because it does not include sufficient information to make a determination, CMS will request additional information within 90 days, or 45 days for applications set forth in § 460.10(a)(2), after the date of submission of the application.

(1) The time limits in paragraph (a) of this section do not begin until CMS receives all requested information and the application is complete.

(2) If more than 12 months elapse between the date of initial submission of the application and the entity's response to the CMS request for additional information, the entity must update the application to provide the most current information and materials related to the application.

(d) *Deemed approval.* An entity's application to become a PACE organization is deemed approved if CMS fails to act on the complete application within 90 days, after the later of the following dates:

(1) The date the application is submitted by the organization.

(2) The date CMS receives all requested additional information.

(e) *Date of submission.* For purposes of the time limits described in this section, the date that an application is submitted to CMS is the date on which the application is delivered to the address designated by CMS.

§ 460.22 [Removed]

■ 9. Section 460.22 is removed.

■ 10. Section 460.26 is amended by revising paragraphs (a) and (b) introductory text to read as follows:

§ 460.26 Submission and evaluation of waiver requests.

(a) A PACE organization, or an entity submitting an application to become a PACE organization, must submit its waiver request through the State administering agency for initial review.

(1) The State administering agency forwards a PACE organization's waiver requests to CMS along with any concurrence, concerns or conditions regarding the waiver.

(2) Entities submitting an application to become a PACE organization may:

(i) Submit a waiver request as a document separate from the application by submitting it first to the State administering agency which, in turn, will forward the waiver request to CMS indicating the State's concurrence, concerns or conditions regarding the waiver request; or

(ii) Submit a waiver request directly to CMS in conjunction with the application. This request must include a letter from the State administering agency indicating the State's concurrence, concerns or conditions regarding the waiver request.

(b) CMS evaluates a waiver request from a PACE organization or PACE applicant on the basis of the following information:

* * * * *

■ 11. Section 460.28 is revised to read as follows:

§ 460.28 Notice of CMS determination on waiver requests.

(a) *General.* Within 90 days after receipt of a complete waiver request, CMS takes one of the following actions, in the form and manner specified by CMS:

(1) Approves the waiver request.

(2) Conditionally approves the waiver request and notifies the PACE applicant.

(3) Denies the waiver request and notifies the PACE organization or PACE applicant of the basis for the denial.

(b) *Additional information requested.* A waiver request is only considered complete when CMS receives all information necessary to make a determination regarding approval or denial. If CMS determines that the waiver request is not complete because it does not include sufficient information to make a determination, CMS will request additional information from the PACE organization or PACE applicant. The 90-day time limit in paragraph (a) of this section will start when CMS receives the complete waiver request.

(c) *Waiver approval.* A waiver request is deemed approved if CMS fails to act on the request within 90 days after CMS receives a complete waiver request.

(d) *Withdrawal of CMS approval for good cause.* (1) CMS in consultation with the State administering agency may withdraw approval of a waiver for good cause.

(2) If the waiver approval is withdrawn, CMS must notify the PACE organization or PACE applicant and the State administering agency that approval of a waiver has been withdrawn and the reason for doing so and must specify the effective date of the withdrawal in the notice.

■ 12. Section 460.32 is amended by revising paragraphs (a)(9) and (12) to read as follows:

§ 460.32 Content and terms of PACE program agreement.

(a) * * *

(9) A description of the organization's quality improvement program.

* * * * *

(12) The state's Medicaid capitation rate or Medicaid payment rate methodology, and the methodology used to calculate the Medicare capitation rate.

* * * * *

■ 13. Section 460.40 amended by—

■ a. Redesignating the introductory text and paragraphs (a) through (e), (f) introductory text, (f)(1) and (2), and (g) through (j) as paragraphs (a) introductory text and (a)(1) through (5), (6) introductory text, (6)(i) and (ii), and (7) through (10) respectively; and

■ b. Adding new paragraph (b).

The addition reads as follows:

§ 460.40 Violations for which CMS may impose sanctions.

* * * * *

(b) If CMS or the State administering agency makes a determination that could lead to termination of a PACE program agreement under § 460.50, CMS may impose any of the sanctions specified at §§ 460.42 and 460.46.

■ 14. Section 460.46 is amended—

■ a. By revising paragraph (a) introductory text.

■ b. In paragraph (a)(1) by removing the reference ''§ 460.40(c) or (d)'' and adding in its place the reference ''§ 460.40(a)(3) or (4)'';

■ c. In paragraph (a)(2) by removing the reference ''§ 460.40(e)'' and adding in its place the reference ''§ 460.40(a)(5)''; and

■ d. In paragraph (a)(3) by removing the reference ''§ 460.40(f)(1)'' and adding in

its place the reference ''§ 460.40(a)(6)(i)''.

The revision reads as follows:

§ 460.46 Civil money penalties.

(a) CMS may impose civil money penalties up to the maximum amounts specified in paragraphs (a)(1) through (4) of this section. These amounts will be adjusted in accordance with the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of Pub. L. 114–74) and updated amounts specified in 45 CFR part 102.

* * * * *

■ 15. Section 460.60 is amended by—

■ a. Removing paragraph (a);

■ b. Redesignating paragraphs (b), (c) and (d) as paragraphs (a), (b), and (c);

■ c. Revising newly redesignated paragraphs (b) and (c)(3);

■ d. Adding new paragraph (d).

The revisions and addition read as follows:

§ 460.60 PACE organizational structure.

* * * * *

(b) *Medical director.* The organization must employ, or contract with in accordance with § 460.70, a medical director who is responsible for the delivery of participant care, for clinical outcomes, and for the implementation, as well as oversight, of the quality improvement program.

(c) * * *

(3) Except as provided in paragraph (d) of this section, a PACE organization planning a change in organizational structure must notify CMS and the State administering agency, in writing, at least 14 days before the change takes effect.

(d) *Change of ownership.* A PACE organization planning a change of ownership must comply with all requirements in 42 CFR part 422, subpart L, and must notify CMS and the State administering agency, in writing, at least 60 days before the anticipated effective date of the change.

■ 16. Section 460.62 is amended by revising paragraph (a)(7) to read as follows:

§ 460.62 Governing body.

(a) * * *

(7) A quality improvement program as described in § 460.130.

* * * * *

■ 17. Section 460.63 is added to read as follows:

§ 460.63 Compliance oversight requirements.

A PACE organization must adopt and implement effective compliance oversight requirements, which must include measures that prevent, detect, and correct non-compliance with CMS' program requirements, as well as measures that prevent, detect, and correct fraud, waste, and abuse. The compliance oversight program must, at a minimum, include establishment and implementation of procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensure ongoing compliance with CMS requirements.

(a) If the PACE organization discovers evidence of misconduct related to payment or delivery of items or services, it must conduct a timely, reasonable inquiry into that conduct.

(b) The PACE organization must conduct appropriate corrective actions (for example, repayment of overpayments, disciplinary actions against responsible employees) in response to the potential violation.

(c) The PACE organization should have procedures to voluntarily self-report potential fraud or misconduct related to the PACE program to CMS and the State administering agency.

■ 18. Section 460.64 is amended by revising paragraphs (a) introductory text, (a)(3), and (4) to read as follows:

§ 460.64 Personnel qualifications for staff with direct participant contact.

(a) *General qualification requirements.* Each member of the PACE organization's staff (employee or contractor) that has direct contact with participants must meet the following conditions:

* * * * *

(3) Have 1 year of experience working with a frail or elderly population or, if the individual has less than 1 year of experience but meets all other requirements under paragraph (a) of this section, must receive appropriate training from the PACE organization on working with a frail or elderly population upon hiring.

(4) Meet a standardized set of competencies for the specific position description established by the PACE organization before working independently.

* * * * *

§ 460.66 [Amended]

■ 19. Section 460.66 is amended by removing paragraphs (b) and (c) and removing the paragraph designation from paragraph (a).

■ 20. Section 460.68 is amended—

■ a. In paragraph (a)(2) by removing the word ''or'' after '';'';

■ b. By revising paragraph (a)(3); and

■ c. Adding paragraphs (a)(4) and (5).

The revision and additions read as follows:

§ 460.68 Program integrity.

(a) * * *

(3) If the PACE organization determines that an individual's contact with participants would pose a potential risk because the individual has been convicted of one or more criminal offenses related to physical, sexual, drug, or alcohol abuse or use;

(4) Who have been found guilty of abusing, neglecting, or mistreating individuals by a court of law or who have had a finding entered into the State nurse aide registry concerning abuse, neglect, mistreatment of residents, or misappropriation of their property; or

(5) Who have been convicted of specific crimes for any offense described in section 1128(a) of the Social Security Act.

* * * * *

■ 21. Section 460.70 is amended—

■ a. By revising paragraph (b)(1)(iii);

■ b. By redesignating paragraphs (d)(5)(vi) through (ix) as paragraphs (d)(6)(i) through (iv);

■ c. By adding paragraph (d)(6) introductory text;

■ d. By revising newly redesignated paragraphs (d)(6)(i), (ii) and (iii);

■ e. In paragraph (e), by removing the term ''PACE Center services'' and adding in its place the term ''PACE center services'' wherever it appears; and

■ f. In paragraph (e)(2) by removing the reference ''§ 460.98(d)'' and adding in its place the reference ''§ 460.98(c)''.

The revisions and addition read as follows:

§ 460.70 Contracted services.

* * * * *

(b) * * *

(1) * * *

(iii) A contractor must comply with the requirements of this part with respect to service delivery, participant rights, and quality improvement activities.

* * * * *

(d) * * *

(6) With respect to an individual who is contracting as a program director or medical director or to be part of the interdisciplinary team as set forth at § 460.60(a) and (b) and § 460.102(b), the contract must specify that the individual agrees to:

(i) Perform all the duties related to its position as specified in this part.

(ii) Participate in interdisciplinary team meetings as required.

(iii) Be accountable to the PACE organization.

* * * * *

■ 22. Section 460.71 is amended by revising paragraphs (a)(1) and (b)(4), and adding paragraphs (c) and (d) to read as follows:

§ 460.71 Oversight of direct participant care.

(a) * * *

(1) The PACE organization must provide each employee and all contracted staff with an orientation that includes, at a minimum, the organization's mission, philosophy, policies on participant rights, emergency plan, ethics, the PACE benefit, and any policies related to the job duties of specific staff.

* * * * *

(b) * * *

(4) Be medically cleared for communicable diseases and have all immunizations up-to-date before engaging in direct participant contact as required under § 460.64(a)(5).

* * * * *

(c) The PACE organization must develop a training program for each personal care attendant to establish the individual's competency in furnishing personal care services and specialized skills associated with specific care needs of individual participants.

(d) Personal care attendants must exhibit competency before performing personal care services independently.

■ 23. Section 460.82 is amended by revising paragraphs (c)(1), (e) introductory text, (e)(3), (e)(4), (e)(5) and removing paragraph (f) to read as follows:

§ 460.82 Marketing.

* * * * *

(c) * * *

(1) In English and in any other principal languages of the community, as determined by the State in which the PACE organization is located. In the absence of a State standard, a principal language of the community is any language that is spoken in the home by at least 5 percent of the individuals in the PACE organization's service area.

* * * * *

(e) *Prohibited marketing practices.* A PACE organization must not use the following marketing practices, which are prohibited:

* * * * *

(3) Gifts or payments to induce enrollment, unless the gifts are of nominal value as defined in CMS guidance, are offered to all potential enrollees without regard to whether they enroll in the PACE program, and are not in the form of cash or other monetary rebates.

(4) Marketing by any individual or entity that is directly or indirectly compensated by the PACE organization based on activities or outcomes unless the individual or entity has been appropriately trained on PACE program requirements, including but not limited to, subparts G and I of this part.

(i) PACE organizations are responsible for the activities of contracted individuals or entities who market on their behalf.

(ii) PACE organizations that choose to use contracted individuals or entities for marketing purposes must develop a method to document training has been provided.

(5) Unsolicited door-to-door marketing or other unsolicited means of direct contact, including calling or emailing a potential or current participant without the individual initiating the contact.

■ 24. Section 460.98 is amended—

■ a. By revising paragraphs (c)(1);

■ b. In paragraph (d) heading by removing the term ''Pace Center'' and adding in its place the term ''PACE center''; and

■ c. In paragraph (d)(3) by removing the term ''Pace center'' and adding in its place the term ''PACE center''.

The revision reads as follows:

§ 460.98 Service delivery.

* * * * *

(c) * * *

(1) Primary care, including services furnished by a primary care provider as defined in § 460.102(c) and nursing services.

* * * * *

§ 460.100 [Amended]

■ 25. Section 460.100 is amended in paragraph (e)(3)(i) by removing the term ''POs'' and adding in its place the term ''PACE organizations,'' and by removing the term ''PO'' and adding in its place the term ''PACE organization''.

■ 26. Section 460.102 is amended by—

■ a. Revising paragraphs (a)(1), (b) introductory text, (b)(1), (c) introductory text, (c)(1), and (c)(2) introductory text;

■ b. Removing paragraph (d)(3);

■ c. Redesignating paragraph (e) as paragraph (f); and

■ d. Adding paragraph (e).

The revisions and additions read as follows:

§ 460.102 Interdisciplinary team.

(a) * * *

(1) Establish an interdisciplinary team, composed of members that fill the roles described in paragraph (b) of this section, at each PACE center to comprehensively assess and meet the individual needs of each participant.

* * * * *

(b) *Composition of interdisciplinary team.* The interdisciplinary team must be composed of members qualified to fill, at minimum, the following roles, in accordance with CMS guidelines. One individual may fill two separate roles on the interdisciplinary team where the individual meets applicable state licensure requirements and is qualified to fill the two roles and able to provide appropriate care to meet the needs of participants.

(1) Primary care provider.

* * * * *

(c) *Primary care provider.* (1) Primary medical care must be furnished to a participant by any of the following:

(i) A primary care physician.

(ii) A community-based physician.

(iii) A physician assistant who is licensed in the State and practices within his or her scope of practice as defined by State laws with regard to oversight, practice authority and prescriptive authority.

(iv) A nurse practitioner who is licensed in the State and practices within his or her scope of practice as defined by State laws with regard to oversight, practice authority and prescriptive authority.

(2) Each primary care provider is responsible for the following:

* * * * *

(e) *Team member qualifications.* The PACE organization must ensure that all members of the interdisciplinary team have appropriate licenses or certifications under State law, act within the scope of practice as defined by State laws, and meet the requirements set forth in § 460.71.

* * * * *

■ 27. Section 460.104 is amended by—

■ a. Revising paragraphs (a)(1), (a)(2) introductory text, (a)(2)(i), (3), (4) introductory text, (b), (c), (d) introductory text, (d)(1) and (d)(2) introductory text;

■ b. Redesignating paragraphs (d)(2)(i) through (v) as paragraphs (d)(2)(ii) through (vi);

■ c. Adding new paragraph (d)(2)(i).

The revisions and additions read as follows:

§ 460.104 Participant assessment.

(a) * * *

(1) *Basic requirement.* The interdisciplinary team must conduct an initial in-person comprehensive assessment on each participant. The assessment must be completed in a

timely manner in order to meet the requirements in paragraph (b) of this section.

(2) *Members present.* As part of the initial comprehensive assessment, each of the following members of the interdisciplinary team must evaluate the participant in person and develop a discipline-specific assessment of the participant's health and social status:

(i) Primary care provider

* * * * *

(3) *Additional professional disciplines.* At the recommendation of the interdisciplinary team, other professional disciplines (for example, speech-language pathology, dentistry, or audiology) may be included in the initial comprehensive assessment process.

(4) *Initial comprehensive assessment criteria.* The initial in-person comprehensive assessment must at a minimum include the evaluation of:

* * * * *

(b) *Development of plan of care.* Within 30 days of the date of enrollment, the interdisciplinary team must consolidate discipline-specific assessments into a single plan of care for each participant through team discussions and consensus of the entire interdisciplinary team. In developing the plan of care:

(1) If the interdisciplinary team determines that certain services are not necessary to the care of a participant, the reasoning behind this determination must be documented in the plan of care.

(2) Female participants must be informed that they are entitled to choose a qualified specialist for women's health services from the PACE organization's network to furnish routine or preventive women's health services.

(c) *Semi-annual reassessment.* On at least a semi-annual basis, or more often if a participant's condition dictates, the following members of the interdisciplinary team must conduct an in-person reassessment:

(1) Primary care provider.

(2) Registered nurse.

(3) Master's-level social worker.

(4) Other team members that the primary care provider, registered nurse and Master's-level social worker determine are actively involved in the development or implementation of the participant's plan of care.

(d) *Unscheduled reassessments.* In addition to semi-annual reassessments, unscheduled reassessments may be required based on the following:

(1) *A change in participant status.* If the health or psychosocial status of a participant changes, the members of the interdisciplinary team listed in paragraph (c) of this section must conduct an in-person reassessment.

(2) *At the request of the participant or designated representative.* If a participant (or his or her designated representative) believes that the participant needs to initiate, eliminate, or continue a particular service, the appropriate members of the interdisciplinary team, as identified by the interdisciplinary team, must conduct a reassessment. The interdisciplinary team member(s) may conduct the reassessment via remote technology when the interdisciplinary team determines that the use of remote technology is appropriate and the service request will likely be deemed necessary to improve or maintain the participant's overall health status and the participant or his or her designated representative agrees to the use of remote technology.

(i) An in-person reassessment must be conducted:

(A) When participant or his or her designated representative declines the use of remote technology.

(B) Before a PACE organization can deny a service request.

* * * * *

■ 28. Section 460.106 is amended by revising paragraph (a) and by adding paragraphs (b)(3), (4), and (5) to read as follows:

§ 460.106 Plan of care.

(a) *Basic requirement.* Within 30 days of the date of enrollment, the interdisciplinary team members specified in § 460.104(a)(2) must develop a comprehensive plan of care for each participant based on the initial comprehensive assessment findings.

(b) * * *

(3) Utilize the most appropriate interventions for each care need that advances the participant toward a measurable goal and outcome.

(4) Identify each intervention and how it will be implemented.

(5) Identify how each intervention will be evaluated to determine progress in reaching specified goals and desired outcomes.

* * * * *

■ 29. Section 460.112 is amended by—

■ a. Revising paragraph (b)(1)(i);

■ b. Removing paragraph (b)(1)(ii);

■ c. Redesignating paragraph (b)(1)(iii) as paragraph (b)(1)(ii); and

■ d. Revising paragraphs (b)(3) and (c)(3).

The revisions read as follows:

§ 460.112 Specific rights to which a participant is entitled.

* * * * *

(b) * * *

(1) * * *

(i) Prior to and upon enrollment in the PACE organization.

* * * * *

(3) To examine, or upon reasonable request, to be helped to examine the results of the most recent review of the PACE organization conducted by CMS or the State administering agency and any plan of correction in effect.

(c) * * *

(3) To disenroll from the program at any time and have such disenrollment be effective the first day of the month following the date the PACE organization receives the participant's notice of voluntary disenrollment as set forth in § 460.162(a).

* * * * *

■ 30. Section 460.116 is amended by revising paragraphs (c)(1) and (2) to read as follows:

§ 460.116 Explanation of rights.

* * * * *

(c) * * *

(1) Write the participant rights in English, and in any other principal languages of the community, as determined by the State in which the PACE organization is located. In the absence of a State standard, a principal language of the community is any language that is spoken by at least 5 percent of the individuals in the PACE organization's service area.

(2) Display the PACE participant rights in a prominent place in the PACE center.

§ 460.120 [Amended]

■ 31. Section 460.120 is amended in paragraph (f) by removing the phrase ''quality assessment and performance improvement'' and adding in its place the phrase ''quality improvement''.

■ 32. Section 460.122 is amended by revising paragraphs (c)(1) and (i) to read as follows:

§ 460.122 PACE organization's appeals process.

* * * * *

(c) * * *

(1) Timely preparation and processing of a written denial of coverage or payment as provided in § 460.104(d)(2)(iv).

* * * * *

(i) *Analyzing appeals information.* A PACE organization must maintain, aggregate, and analyze information on appeal proceedings and use this information in the organization's internal quality improvement program.

■ 33. Subpart H is amended by revising the heading to read as follows:

Subpart H—Quality Improvement

■ 34. Section 460.130 is amended by revising paragraph (a) and adding paragraph (d) to read as follows:

§ 460.130 General rule.

(a) A PACE organization must develop, implement, maintain, and evaluate an effective, data-driven quality improvement program.

* * * * *

(d) A PACE organization must meet external quality assessment and reporting requirements, as specified by CMS or the State administering agency, in accordance with § 460.202.

■ 35. Section 460.132 is amended by revising the section heading and paragraphs (a) and (c)(3) to read as follows:

§ 460.132 Quality improvement plan.

(a) *Basic rule.* A PACE organization must have a written quality improvement plan that is collaborative and interdisciplinary in nature.

* * * * *

(c) * * *

(3) Document and disseminate to PACE staff and contractors the results from the quality improvement activities.

§ 460.134 [Amended]

■ 36. Section 460.134 is amended in the section heading and paragraph (a) introductory text by removing the term ''quality assessment and performance improvement'' and adding in its place the term ''quality improvement''.

§ 460.136 [Amended]

■ 37. Section 460.136 is amended by—

■ a. In the section heading and paragraphs (b), (c) introductory text, (c)(1), and (c)(2) by removing the term ''quality assessment and performance improvement'' and adding in its place the term ''quality improvement''.

■ b. In paragraphs (a) heading and (b) heading by removing the term ''Quality assessment and performance improvement'' and adding in its place the term ''Quality improvement''.

§ 460.138 [Amended]

■ 38. Section 460.138 is amended in paragraph (b) by removing the term ''quality assessment and performance improvement'' and replacing it with ''quality improvement''.

§ 460.140 [Removed]

■ 39. Section 460.140 is removed.

■ 40. Section 460.150 is amended by revising paragraph (c)(2) to read as follows:

§ 460.150 Eligibility to enroll in a PACE program.

* * * * *

(c) * * *

(2) The State administering agency criteria used to determine if an individual's health or safety would be jeopardized by living in a community setting must be specified in the program agreement.

* * * * *

■ 41. Section 460.152 is amended by revising paragraph (b)(4) to read as follows:

§ 460.152 Enrollment process.

* * * * *

(b) * * *

(4) Notify CMS and the State administering agency in the form and manner specified by CMS and make the documentation available for review.

■ 42. Section 460.154 is amended by revising paragraph (i) to read as follows:

§ 460.154 Enrollment agreement.

* * * * *

(i) Notification that enrollment in PACE results in disenrollment from any other Medicare or Medicaid prepayment plan or optional benefit. Electing enrollment in any other Medicare or Medicaid prepayment plan or optional benefit, including the hospice benefit, after enrolling as a PACE participant is considered a voluntary disenrollment from PACE. If a Medicaid-only or private pay participant becomes eligible for Medicare after enrollment in PACE, the participant will be disenrolled from PACE if he or she elects to obtain Medicare coverage other than from the participant's PACE organization.

* * * * *

■ 43. Section 460.156 is amended by revising paragraph (a)(2) and removing paragraph (a)(4) to read as follows:

§ 460.156 Other enrollment procedures.

(a) * * *

(2) A PACE membership card that indicates that he or she is a PACE participant and that includes the phone number of the PACE organization.

* * * * *

■ 44. Section 460.162 is revised to read as follows:

§ 460.162 Voluntary disenrollment.

(a) *Effective date.* A participant's voluntary disenrollment is effective on the first day of the month following the date the PACE organization receives the participant's notice of voluntary disenrollment.

(b) *Reasons for voluntary disenrollment.* A PACE participant may voluntarily disenroll from the program without cause at any time.

(c) *Responsibilities of PACE organization.* A PACE organization must ensure that its employees or contractors do not engage in any practice that would reasonably be expected to have the effect of steering or encouraging disenrollment of participants due to a change in health status.

■ 45. Section 460.164 is amended—

■ a. By redesignating paragraphs (a) through (e) as paragraphs (b) through (f), respectively;

■ b. By adding new paragraph (a);

■ c. By revising newly redesignated paragraph (b)(1);

■ d. By redesignating newly redesignated paragraphs (b)(2) through (6) as paragraphs (b)(4) through (8), respectively;

■ e. By adding new paragraphs (b)(2) and (3);

■ f. In newly redesignated paragraph (b)(4) by removing the reference ''paragraph (b)'' and by adding in its place the reference ''paragraph (c)''; and

■ g. By revising newly redesignated paragraphs (c) and (d).

The revisions and additions read as follows:

§ 460.164 Involuntary disenrollment.

(a) *Effective date.* A participant's involuntary disenrollment occurs after the PACE organization meets the requirements set forth in this section and is effective on the first day of the next month that begins 30 days after the day the PACE organization sends notice of the disenrollment to the participant.

(b) * * *

(1) The participant, after a 30-day grace period, fails to pay or make satisfactory arrangements to pay any premium due the PACE organization.

(2) The participant, after a 30-day grace period, fails to pay or make satisfactory arrangements to pay any applicable Medicaid spend down liability or any amount due under the post-eligibility treatment of income process, as permitted under §§ 460.182 and 460.184.

(3) The participant or the participant's caregiver engages in disruptive or threatening behavior, as described in paragraph (c) of this section.

* * * * *

(c) *Disruptive or threatening behavior.* (1) For purposes of this section, a participant who engages in disruptive or threatening behavior refers to a participant who exhibits either of the following:

(i) A participant whose behavior jeopardizes his or her health or safety, or the safety of others; or

(ii) A participant with decision-making capacity who consistently

refuses to comply with his or her individual plan of care or the terms of the PACE enrollment agreement.

(2) For purposes of this section, a participant's caregiver who engages in disruptive or threatening behavior exhibits behavior that jeopardizes the participant's health or safety, or the safety of the caregiver or others.

(d) *Documentation of disruptive or threatening behavior.* If a PACE organization proposes to disenroll a participant based on the disruptive or threatening behavior of the participant or the participant's caregiver, the organization must document the following information in the participant's medical record:

(1) The reasons for proposing to disenroll the participant.

(2) All efforts to remedy the situation.

* * * * *

■ 46. Section 460.166 is amended by revising the section heading to read as follows:

§ 460.166 Disenrollment responsibilities.

* * * * *

■ 47. Section 460.168 is amended by revising paragraph (a) to read as follows:

§ 460.168 Reinstatement in other Medicare and Medicaid programs.

* * * * *

(a) Make appropriate referrals and ensure medical records are made available to new providers within 30 days.

* * * * *

§ 460.172 [Amended]

■ 48. Section 460.172 is amended in paragraph (c) by removing the reference ''quality assessment and performance improvement'' and adding in its place the reference ''quality improvement''.

■ 49. Section 460.182 is amended by revising paragraph (b) introductory text to read as follows:

§ 460.182 Medicaid payment.

* * * * *

(b) The monthly capitation amount is negotiated between the PACE organization and the State administering agency, and the amount, or the methodology used to calculate the amount, is specified in the PACE program agreement. The amount represents the following:

* * * * *

■ 50. Section 460.190 is amended by—

■ a. Revising paragraph (b)(1);

■ b. Redesignating paragraphs (b)(2) through (4) as paragraphs (b)(3) through (5); and

■ c. Adding a new paragraph (b)(2).

The revision and addition read as follows:

§ 460.190 Monitoring during trial period.

* * * * *

(b) * * *

(1) An onsite visit to the PACE organization, which may include, but is not limited to, observation of program operations;

(2) Detailed analysis of the entity's substantial compliance with all significant requirements of sections 1894 and 1934 of the Act and this part, which may include review of marketing, participant services, enrollment and disenrollment, and grievances and appeals.

* * * * *

■ 51. Section 460.192 is amended by revising paragraph (b) to read as follows:

§ 460.192 Ongoing monitoring after trial period.

* * * * *

(b) CMS in cooperation with the State administering agency will conduct reviews of the operations of PACE organizations as appropriate, as determined by a risk assessment of each PACE organization which takes into account the PACE organization's performance level and compliance with the significant requirements of sections 1834 and 1934 of the Social Security Act and this part.

■ 52. Section 460.194 is amended by revising paragraph (a) to read as follows:

§ 460.194 Corrective action.

(a) A PACE organization must take action to correct deficiencies identified by CMS or the State administering agency through the following:

(1) Ongoing monitoring of the PACE organization.

(2) Reviews and audits of the PACE organization.

(3) Complaints from PACE participants or caregivers.

(4) Any other instance CMS or the State administering agency identifies programmatic deficiencies requiring correction.

* * * * *

■ 53. Section 460.196 is amended by revising paragraph (d) to read as follows:

§ 460.196 Disclosure of review results.

* * * * *

(d) The PACE organization must make the review results available for examination in a place readily accessible to participants, their families, their caregivers, and their authorized representatives.

■ 54. Section 460.200 is amended by revising paragraphs (f)(1)(ii) and (iii) to read as follows:

§ 460.200 Maintenance of records and reporting of data.

* * * * *

(f) * * *

(1) * * *

(ii) Ten years from the last entry date.

(iii) For medical records of disenrolled participants, 10 years after the date of disenrollment.

* * * * *

Dated: March 15, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: April 3, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2019–11087 Filed 5–28–19; 4:15 pm]

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Federal Register

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CFR PARTS AFFECTED DURING JUNE

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Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

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This table is used by the Office of the Federal Register to compute certain dates, such as effective dates and comment deadlines, which appear in agency documents. In computing these dates, the day after publication is counted as the first day.

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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June 13	Jun 28	Jul 5	Jul 15	Jul 18	Jul 29	Aug 12	Sep 11
June 14	Jul 1	Jul 5	Jul 15	Jul 19	Jul 29	Aug 13	Sep 12
June 17	Jul 2	Jul 8	Jul 17	Jul 22	Aug 1	Aug 16	Sep 16
June 18	Jul 3	Jul 9	Jul 18	Jul 23	Aug 2	Aug 19	Sep 16
June 19	Jul 5	Jul 10	Jul 19	Jul 24	Aug 5	Aug 19	Sep 17
June 20	Jul 5	Jul 11	Jul 22	Jul 25	Aug 5	Aug 19	Sep 18
June 21	Jul 8	Jul 12	Jul 22	Jul 26	Aug 5	Aug 20	Sep 19
June 24	Jul 9	Jul 15	Jul 24	Jul 29	Aug 8	Aug 23	Sep 23
June 25	Jul 10	Jul 16	Jul 25	Jul 30	Aug 9	Aug 26	Sep 23
June 26	Jul 11	Jul 17	Jul 26	Jul 31	Aug 12	Aug 26	Sep 24
June 27	Jul 12	Jul 18	Jul 29	Aug 1	Aug 12	Aug 26	Sep 25
June 28	Jul 15	Jul 19	Jul 29	Aug 2	Aug 12	Aug 27	Sep 26